East Liverpool QA Materials

QA MATERIALS

Table of Contents

IRB PROTOCOL

San Francisco State University 8/1/11
An Epidemiologic Health Study of Manganese Exposure in adult residents of East Liverpool, Ohio
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1. STUDY AIM, BACKGROUND AND DESIGN

The proposed study aims to answer the following questions:

- Is external Mn exposure (Mn-air) associated with biomarkers of internal Mn dose [Mn in blood (Mn-B), toenails (Mn-T), hair (Mn-H)] and neuropsychological and neurological function in adults?
- Does the neuropsychological function of a group of Mn-exposed adults differ significantly between groups with different levels of exposure to Mn-air?

Exposure Background:

On November 16, 2010 the U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR) presented residents of the town of East Liverpool, adjacent to the Ohio River, with an air quality report describing the potential health risks from ambient metals. Analyses of the U.S. EPA's air monitoring data at three locations in East Liverpool have shown elevated ambient air levels of manganese (Mn) and chromium-III (CrIII) over a period of nine years and eight months (between January 1999 and September 2009). Mn-air levels in East Liverpool (Water plant monitor) were found to be on average about 10 times higher than those in another Mn-exposed Ohio town (Marietta), which, along with a similar non-industrially Mn-exposed town (Mt. Vernon), has been examined recently in a health study conducted by the P.I. and her colleagues. Ohio EPA identified the S.H. Bell Company, a facility that warehouses and packages primarily raw metals (including Mn) from all over the world, as an exposure source contributing to these elevated levels. The present study seeks a) to determine the possible health risks to residents of the high Mn-exposure in East Liverpool, and b) to compare any health effects between the towns (exposed and comparison) currently being studied by this team of investigators.

There is a time urgency to perform a health study of the Mn health risks in East Liverpool because the S.H. Bell Company has been required by Ohio EPA to reduce the community's exposure to Mn emissions. In two Ohio EPA and US EPA enforcement actions, the plant was asked to comply with the following guidelines in order to remain in operation: pave a dirt road on the State Line property, install a dust suppression program, enclose some storage piles, improve dust collection, and tarp all trucks leaving the S.H. Bell facility. The site upgrades were completed in 2008 and it is anticipated that Mn-air will have decreased by the middle of 2011. Ohio EPA also plans to continue the air monitoring and, moreover, have already installed a PM_{10} monitor and plan to install a $PM_{2.5}$ monitor which will assess the respirable fraction of the Mn particles.

The experienced research team proposing this health evaluation is prepared to conduct such a study of East Liverpool residents on short notice because they have already developed epidemiologic methods and applied them in the current health study being completed of the Mn-exposed town of Marietta, Ohio and the unexposed comparison town of Mt. Vernon, Ohio. Relevant health questionnaires - including questions on demographic and residential history,

symptoms and illnesses, environmental characteristics, such as intake of Mn and iron in diet, time spent indoors and outdoors - have already been developed and tested and are appropriate for use in East Liverpool with minimal changes. Ohio Department of Health has pledged to assist the P.I. and study investigators with news media co-ordination and lending state-level support to the study team. Additionally, Dr. Michelle Colledge, who authored the East Liverpool Air Quality Report of November 16, 2010, will collaborate on the analyses of the air Mn exposure (ATSDR, 2010). Advanced staff members from the ATSDR and the U.S. and Region 5 EPA will collaborate with the team of investigators, trained neuropsychological testers, medical experts, and statisticians who have been working conjointly on the Marietta-Mt. Vernon study. They will be available this calendar year (2011) and are willing to work on the proposed on-site applied health research study in East Liverpool. The proposed study offers the opportunity to examine an additional, more highly Mn-exposed community, and to compare the results to the two towns in Ohio under current study.

Exposure source:

Ambient air monitoring has already been conducted at three monitor locations near the S.H. Bell Company in East Liverpool and ambient Mn-air measurements are available from the Ohio EPA and the ATSDR for a period of nine years and eight months.

As described in the East Liverpool Air Quality Report by the ATSDR of November 16, 2010 (ATSDR, 2010), the S.H. Bell Company handles a great volume of raw and processed metal products. S.H. Bell has two locations in East Liverpool, approximately one mile apart: the Little England facility and the State Line facility. Ferrous and nonferrous materials are stored, transferred, and warehoused at both locations. The S.H. Bell Company is equipped to process, dry, crush, screen, and package their ore/materials for industry. Shipping occurs through river barge, truck, and rail. On most days, this includes shipping out 1.5 barges and 100-120 trucks (ATSDR Health Consultation report, 2010). Although the company employed 52 persons in 2007, by 2009, this number decreased to 26 workers. The results of air monitoring reported in the November 2010 East Liverpool Air Quality Report showed highly elevated Mn levels in air (ATSDR, 2010). Only two metals, Mn and Cr were identified as elevated in the air sampled over nine years and eight months. More specifically, all of the identified chromium particulate matter was CrIII – no CrVI was noted. CrIII is not associated with an increased cancer risk and is not considered to be a health concern (ATSDR, 2010). The EPA's computation of a hazard quotient (HQ: ambient concentration divided by the reference concentration of 0.05 $\mu g/m^3$) of 30 indicated the residences near the Water Plant air monitor (S.H. Bell State Line facility) have the highest non-cancer risk, with 99% of the risk "attributed to Mn" (ATSDR, 2010).

The monitors located near the two S.H. Bell facilities in East Liverpool are (See Appendix A of this report and the Air Quality Report of November 16, 2010):

1. **Water Plant** monitor immediately adjacent to the S.H. Bell State Line facility. The air monitor is located approximately 250 feet W from the State Line facility with average Mn TSP concentration of 1.30 $\mu g/m^3$, range 0.10-23.0 $\mu g/m^3$

2. **Maryland Avenue** monitor located about 0.30 miles to the north-northwest of the S.H. Bell Little England facility – with average Mn TSP concentration of 0.18 $\mu g/m^3$, range 0.01-1.0 $\mu g/m^3$

3. **Port Authority** monitor located approximately 0.33 miles to the west-southwest of the

S.H. Bell Little England facility with average Mn TSP concentrations of 0.26 µg/m^3, range 0.02-1.9 µg/m^3

Because the Water Plant monitor clearly shows the highest levels of Mn in air, the area around the water plant in a 2.5 mile radius will be the area studied under the proposed protocol. Additionally, census data indicates that this area has a sufficient number of housing units from which to recruit a random sample of 100.

The EPA has indicated that average Mn concentrations are between 0.04 and 0.05 µg/m^3 in urban areas. The ATSDR also reports average levels in urban areas of 0.05 µg/m^3 and the WHO reports concentrations near industrial Mn sites to be 0.2 to 0.3µg/m^3 . The area around the East Liverpool air monitors is densely populated, making it an ideal natural laboratory to study the health effects of moderately high levels of Mn in air in an environmental setting.

Human Exposure to Manganese:

Manganese is a naturally occurring essential element and low levels of Mn in water, food, and air are ubiquitous. Although Mn is also contained in food, it is thought to be more readily absorbed from water and air. In certain geographic regions, long contact between groundwater and Mn in bedrock can lead to high levels of Mn in water (U.S.EPA, 2004). Industrial plants involved in the refining and processing of Mn ore have higher Mn emissions, which may affect the health of humans residing in close proximity. The Mn exposure route of most concern in the present study is inhalation. Blood biomarkers will reflect all routes of Mn exposure. Diet will be surveyed with a suitable brief diet questionnaire to assess approximate intake of Mn rich foods such as nuts, beans and tea and whole grains (rice, wheat, oats, etc.), but Mn in diet is not considered to have a contribution to adverse health effects. The proposed study will also provide pilot data that will subsequently help conducting an even larger, more comprehensive study by ATSDR at a later date.

In the occupational health literature there are many reports of workers exposed to Mn with adverse health effects. Miners, steel and alloy smelters, chemical plant workers over-exposed to Mn, and iron/steel welders are known to be at risk for developing a pattern of signs and symptoms showing a decline in psychiatric health (i.e. mood disturbance), deterioration of cognitive ability (i.e. problems with attention, memory, and information processing), and a movement disorder similar to Parkinson's disease (PD) (i.e. a disturbance of gait, loss of balance, dystonia, bradykinesia, and tremor) (Bowler et al., 2007).

Environmental studies of airborne Mn have been relatively rare and results of a select few studies have been published. At the first major conference on the effects of long-term, low-level exposure to Mn in Little Rock, Arkansas in 1997, an inter-disciplinary international forum was held on state of the art research data on this issue, which was followed by publication of the peer-reviewed papers presented at that time. In this special April/June 1999 issue of the Journal of NeuroToxicology only 7 out of 33 published papers reported on environmental human exposure to Mn, including exposure to Methylcyclopentadienyl Manganese Tricarbonyl (MMT) (2 publications) and the neuropsychological effects of environmental Mn exposure (5 publications). Lynam et al. (1999) reported no effects of MMT and of ambient air levels of car emissions in Toronto, Canada. Zayed et al. (1999) also reported a lack of effects of potential exposure to MMT in residents near a gas station and underground parking garage, but did report "substantial concentrations of respirable manganese (Mn_R)". Neuropsychological effects of environmental Mn exposure were reported by Mergler et al. (1999) in their study of 273

community residents in Quebec, Canada, for whom a relationship of lower neuropsychological function with higher Mn in blood was found. Higher levels of Mn were also shown to be associated with changes in coordinated upper limb movements and poorer learning and recall. An interaction between Mn and increasing age (>50) was found for motor tasks. Bowler et al. (1999) reviewed the literature on neuropsychiatric effects of Mn on mood and described these effects in the group of 273 community residents in Quebec. These effects were categorized to be anxiety, psychotic experiences, emotional disturbance, fatigue, compulsive behaviors and aggression and hostility. Baldwin et al. (1999) described the bioindicators and exposure data of the Mergler et al. (1999) study and reported that Mn in air samples of total suspended particulate measured at 4 sites, amounted between 0.009 $\mu g/m^3$ and 0.035 $\mu g/m^3$. These levels of Mn in air are considerably lower than those in East Liverpool.

Studies by Lucchini et al. (2007) report an increased prevalence of parkinsonian disorders associated with Mn exposure in the vicinities of ferroalloy industries in Northern Italy. Concentrations of Mn in settled dust measured in 206 municipalities were significantly higher near and downwind from two of four industrial plants. Near one of the four plants studied, airborne concentration of Mn in total dust averaged 300+ 533 $\mu g/m^3$ (range 20-1600). The estimated range of ultrafine $PM_{2.5}$ particles in six locations, within a distance of about 2 km from plant B (Lucchini et al., 2003) were also measured outside the plants in 2001 and showed a geometric mean of 0.69 $\mu g/m^3$ (range 0.2-1.8). The respirable fraction of Mn was reported to be 25% to 90% of the total dust from the plants.

In 2007, Finkelstein and Jerrett (2007) re-visited the concerns over industrial Mn emissions and those due to combustion of gasoline MMT and investigated the association of PD and Mn exposure in 110,000 subjects from Toronto and Hamilton, Canada. They used residential postal codes and did geocoding to assign longitude and latitude coordinates for each resident. Thus, the residential locations were analyzed for distance from a major urban road. Hamilton residents were exposed to both mobile sources of Mn from MMT and industrial Mn emissions from steelmaking industry, while residents in Toronto were without "substantial" industrial emissions of Mn. Manganese in total suspended particulate in Hamilton (TSP-Mn 50.5, to 92.1 ng/m^3) was found to be significantly higher than in Toronto (9 ng/m^3). Results of the prevalence curves for PD indicated that ambient exposure to Mn results in diagnoses of PD at an earlier age, which was postulated to be consistent with the theory that increased Mn exposure would be associated with increased neuronal loss in the aging process.

Although few comprehensive studies of environmental exposure to Mn have been reported, a small body of recent research has associated Mn exposure with learning and neuropsychological deficits in elementary school children. Wasserman et al. (2006) reported dose-effect relationship between concentration of Mn in drinking water and decreased IQ. Likewise, Chinese investigators reported that scores on tests of learning and neuropsychological functions were lower in elementary school children exposed to Mn in drinking water at levels of 241-346 ug/l than in children from a control group with very low Mn levels in drinking water. Levels of Mn in hair correlated with several neuropsychological scores. Additionally Zhang et al. (1995) reported lower levels of serum 5-hydroxytryptamine, dopamine, norepinephrine and acetylcholine esterase in the exposed children. Bouchard et al. (2007) reported a significant relation between levels of Mn in water and hair of children as well as an increase in indicators of hyperactive behaviors with Mn in hair.

In conclusion, although recent studies on children exposed to Mn- through drinking water show decrements in neuropsychological performance, none of the recent environmental studies

on adults included a comprehensive neuropsychological test battery in the context of air measurements, such as those detailed in the East Liverpool air reports. Only the earlier work by Mergler et al. (1999) related Mn in air to neuropsychological function. This present study seeks to fill that gap and will utilize past knowledge gained from these studies by using a more refined and recently updated neuropsychological test battery, including the Computerized Adaptive Testing System (CATSYS) to assess hand tremor and body sway, in addition to geo-coded data in relation to the Mn air results already performed by ATSDR and EPA in East Liverpool, Ohio.

BACKGROUND

Air monitoring at the three locations near the S.H. Bell Company in East Liverpool has already been conducted by the Ohio EPA and the ATSDR over a period of over 9 years. This proposed project is to be conducted with a randomly selected sample of adult residents aged 30-75 years (under a contract between SFSU and the US EPA with partial in-kind contributions of personnel from the ATSDR and EPA). Randomly selected study participants will include 100 residents, selected from a purchased list of addresses in East Liverpool, OH, within a perimeter of 2.5 miles from the Water Plant air monitor. This study will include neurological and neuropsychological evaluations and measures of Mn exposure in air and levels of Mn in biomarkers measured in blood, hair, and toenails. Upon completion, this study will contribute knowledge about the potential risk for health effects associated with the higher ambient Mn air measured in East Liverpool.

East Liverpool has 13,089 residents and is similar in size to the two towns (Marietta: 14,515 residents and Mt. Vernon: 14,375 residents) currently being studied by the investigators (see Appendix C). East Liverpool is also similar to these two towns in ethnic and gender proportions, median age, and income; however, the percentage of residents living below poverty in East Liverpool is higher than in Marietta and Mt. Vernon. The percent of residents having less than a high school education in East Liverpool (26.6%) is higher than in Marietta (15.9%) and Mt. Vernon (19.8%) and fewer residents of East Liverpool are college graduates or have post-graduate degrees. Both Mn-exposed towns, Marietta and East Liverpool, are situated on the Ohio River and both have Mn polluting industries near the city. Both Marietta and East Liverpool have industrial plants with documented chemical emissions, with Mn being the pollutant of greatest concern. The exposed town of Marietta has an industrial complex with a ferroalloys facility, Eramet, being the main point source for Mn emissions. Modeled Mn air emissions in Marietta have been shown to range from 0.04 to 0.96 $\mu g/m^3$; while East Liverpool, the proposed more highly exposed town, has Mn-air concentrations ranging from 0.10-23.0 $\mu g/m^3$. Mn exposure for Mt. Vernon was considered to be low based on data from the Toxic Release Inventory, and the town was therefore selected as a comparison/control town.

Study Design: The proposed health study will utilize a cross-sectional design using a Mn-exposed group of 100 residents of East Liverpool drawn at random as an add-on to the 100 exposed residents from Marietta and 90 comparison residents from Mt. Vernon, who are part of a prior study currently being completed. As for the prior study, the same age group (30-75 years of age), and the same methods of selection/recruitment, inclusion and exclusion criteria, and neurological and neuropsychological test measures and procedures will be used in this current study of East Liverpool, Ohio. The prior study conducted in Marietta and Mt. Vernon, had received IRB approval from both SFSU and the Ohio Department of Health (ODH).

- **Data collection methods:** The same carefully controlled and standardized test administration instructions as those used in the Marietta/Mt Vernon study will be applied to the data collection procedures in East Liverpool. To the extent possible, the testers will be the same as in the prior study. The test battery and test description are listed in Appendix B. All non-copyrighted questionnaires are also submitted to the IRB for approval. Additionally, an IRB protocol will be submitted to the US EPA, who have contracted the University of North Carolina to conduct their IRB reviews.

The data collected in this study will include the following:

1. Air exposure of Mn, already collected by the EPA/ATSDR for the period between 1999 and 2009 (9 years and 8 months).
2. Neuropsychological (including mood and motor efficiency) tests (see Appendix B of the enclosed proposal).
3. Neurological function will be assessed with the Unified Parkinson's Disease Rating Scale (UPDRS) administered by the same trained physician (2 subscales: Activities of Daily Living and Motor Function)
4. The CATSYS (Danish Product Development) – consisting of 4 postural sway conditions and hand tremor.
5. A health questionnaire containing sections on residency, symptoms, medical history, medications, work history and behaviors, diet, and personal demographic information (enclosed).
6. The possibility of worry impacting symptom reporting in the East Liverpool group will be addressed in two ways: A) we will include an Environmental Worry Scale (EWS, enclosed), scores of which will be analyzed as a potential confounder and B) all examiners will be (most already are) trained in detecting symptom and cognitive impairment exaggeration. Additionally, a short test of effort (Rey-15) will be administered, which if failed, will result in the administration of a highly regarded test of symptom validity, the Victoria Symptom Validity Test (VSVT). This test is designed to provide evidence that can confirm or disconfirm the validity of an examinee's cognitive and symptom impairments. In the event that the examinee fails both the Rey 15 and the VSVT, that participant's test scores will be excluded from the group analysis.
7. Whole blood will be analyzed for levels of manganese (Mn), mercury (Hg), cadmium (Cd), and lead (Pb) and serum will be used to evaluate ferritin and the liver enzymes, alanine-aminotransferase (ALT) and gamma-glutamyltransaminase (GGT). Toenail and hair samples will be analyzed for levels of Mn. In total, 12 mL whole blood (2 tubes of 6 mL) will be collected from each participant for analyses. Whole blood samples will be shipped on dry ice by Fed Ex immediately to the CDC and serum samples to the U.S. EPA NHEERL Core laboratories. The samples will be identified by each participant's ID number only and no names will be included

The ATSDR, represented by Dr. Michelle Colledge, will be collaborators on the proposed project to assist on the analysis of the monitoring data from the East Liverpool region. Dr. Danelle Lobdell, an epidemiologist from the U.S. EPA National Health and Environmental Effects Research Laboratory, Human Studies Division, will serve as the Technical Consultant on the project. The data of Mn in air collected over the 9 years and 8 months and published in the

November 2010 Health Consultation report, will be the basis for determining external Mn exposure. Additionally, internal Mn dose will be assessed through the analyses of Mn in blood, hair, and toenail analyses for the presence of Mn in the body. The study of the East Liverpool group will enable the comparison of the residents' neuropsychological test performance, motor efficiency, movement, and function on postural sway and hand tremor with that of the Marietta and Mt. Vernon groups and with established normative data. The information collected from the medical, social, and psychological history questionnaire will be used to control for factors (other than exposure to Mn) that could affect an individual's test performance. The use of standardized and well-recognized tests will also allow us to examine the neuropsychological test performance data in relation to the exposure data (both internal and external) to determine the presence of dose-dependent differences in neuropsychological function.

- **NEUROPSYCHOLOGICAL TESTS AND DESCRIPTIONS**
  The test battery and test descriptions are listed in Appendix B.

- **Data Analysis Plan**

In order to compare scores on neuropsychological, motor and mood tests, and the UPDRS between the three towns, the general linear model will be used. This will test for differences between participants in the three towns, including pairwise comparisons for differences in domains of neurological, neuropsychological, mood and motor functioning, with covariates included in the model as necessary. Logistic regressions will be used for dichotomous outcomes such as symptom and illness frequencies in each town, comparing the relative risk between the samples after controlling for the effects of covariates.

Multiple regression analyses will test for relationships between Mn levels in air, blood, hair, and toenails, and neuropsychological test scores in East Liverpool, and these relationships will be compared to the results recently obtained in Marietta. Logistic regressions will be used for categorical outcomes to examine the relationship between Mn levels in air and risk for particular illnesses or symptoms and mood.

Power analyses using G*Power statistical software indicated adequate statistical sensitivity with a sample size of 100. Setting power at 0.80 and alpha at 0.05, one-way between groups analyses of means would be powered to detect an effect size of f=0.18 or greater. This is halfway between a small and medium effect size based on Cohen's (1988) guidelines, and should be sufficiently sensitive to detect the effects of manganese exposure in this sample, based on theory and previous research.

- **Limitations of the available Exposure Estimates**

The current proposal does not include individual quantitative estimates of actual air Mn exposures but the monthly averages of Mn in air monitored in the area studied will be used to model exposure. Questionnaires and biomarker results will be used to help rule out confounding exposure from other chemicals analyzed in blood and from effect modifiers measured in serum. The understanding is that the current proposal's "exposure assessment" includes only one group of East Liverpool participants residing within 2.5 miles of the Water Plant air monitor who have on average about 10 x greater airborne Mn exposure than residents in Marietta. The basis for this exposure assumption is described above. Dietary information of foods containing Mn, Mn in diet supplements, and Mn in blood, hair, and toenails will be collected and analyzed with the functional variables assessing possible dose-effects. This study is supplemental to the pilot study for the larger proposed ATSDR study and has a narrow focus on neurobehavioral and health

outcomes in relation to Mn in ambient air, blood, hair, and toenails, with diet as an additional surrogate for Mn.

- **Significance:**

1. This study will contribute to the knowledge of effects of environmental exposure at different levels to airborne Mn on neurological and neuropsychological functions of randomly selected adults.
2. Although Mn exposure has been reported in numerous studies of occupational workers, very few reports of environmental Mn exposure are available. This study will add to the findings of the Marietta study by investigating a much higher exposed town, which will contribute to
    - knowledge about environmental Mn data in air and in blood, hair, and toenails, and the level of exposure that may be related to developing symptoms associated with Mn exposure
    - knowledge of the relationship of Mn in air to neurological, neuropsychological, and health status
    - addressing concerns about potential health effects in the exposed town of East Liverpool when comparing the adult test data to that of Marietta and Mt. Vernon and to normative ranges of unexposed populations
    - piloting and refining the study methodology for a larger study being planned by the ATSDR

2. PARTICIPANT POPULATION

a. Participants: The proposed health study will recruit 110 individuals (10 will be alternates if there are cancellations) residing within 2.5 miles of the Water Plant air monitor in East Liverpool, Ohio. Due to the demographic similarities between East Liverpool and the two communities already studied, the selected participants are expected to be similar on age, gender, ethnicity, and level of education (Appendix C).

b. Inclusion criteria

To be included in the study, participants must be 30-75 years old and have 10 years or more of residency in East Liverpool. Participants must live in homes serviced by the municipal water supply and must reside within 2.5 miles of the Water Plant air monitor in East Liverpool, Ohio.

c. Exclusion criteria

1. having had a major occupational exposure to pesticides, fungicides, or herbicides, carbon monoxide (CO), or other heavy metals requiring a medical visit,

2. a diagnosis of a psychiatric, neurological, or hepatic medical condition, including: stroke, electroconvulsive treatment, epilepsy, brain surgery, encephalitis, meningitis, multiple sclerosis, Parkinson's disease, Huntington's chorea, Alzheimer's dementia, schizophrenia, bipolar disorder,

3. current treatment for alcohol or drug dependence,

4. prior head injury or a stroke resulting in hospitalization for more than 1 day,

5. having worked at S.H. Bell or Eramet Marietta Inc. at any time,

6. women who are pregnant or nursing.

RECRUITMENT

Participant recruitment will be preceded by public announcements of the study. The recruitment plan is outlined below.

a) Community Meetings and Health Study Announcements

1. Community meeting announcements will be made via radio, newspaper, and television.
2. The study P.I. and her assistant will travel to East Liverpool on September 14th, 2011 to meet with the Health Commissioner and her board, on September 15, 2011, presenting the study. The same evening, a meeting for the community will be held to describe the study as outlined below in # 3 open to the residents and other interested parties of East Liverpool.
3. The community meeting in East Liverpool will consist of a presentation of a brief slide show, previously presented at the Marietta, Ohio community meeting but revised for East Liverpool. Around the time of the community meeting, invitation letters will be mailed to all residents within a 1 mile radius of the Water Tower monitor and to a random sample of approximately 1/3 East Liverpool households within the 1-2.5 mile area, selected at random form a purchased list of postal addresses. The letter will describe the East Liverpool Community Health Study and its procedures. The letters will also contain a stamped, self-addressed postcard where residents will be able to indicate their interest in study participation if they are eligible (determined by a phone call interview after the cards are received in the research office).

b) Recruitment Procedure:

1. The sample of households in the area of 2.5 miles surrounding the East Liverpool Water Plant air monitor and S.H. Bell will be obtained from the 911 database, and a purchased list of all complete postal addresses.
2. Letters will be mailed to all residents within the 1 mile area from the Water Plant air monitor and a randomly selected group of addresses representing 1/3 of the database containing the postal addresses for the 1-2.5 mile area. The letters will contain a self-addressed, stamped card which could be used to indicate willingness to participate or denial to participate in the health study. If participants indicated interest, a brief questionnaire listing the exclusion factors will be administered during subsequent telephone calls to the participants. If the number of return cards received 2 weeks after the mail out is insufficient, the research team will attempt to contact potential participants via telephone. In an attempt to reach potential participants, a maximum of three phone calls will be made to those who have an answering machine and a maximum of five phone calls for those who do not have an answering machine. The telephone numbers will be obtained from an East Liverpool telephone book or the white pages. If the responses are insufficient in number, this process will be repeated until 110 adults are available to be tested or until the maximum number of phone calls has been reached for each potential participant (10 alternates are included to be called if any of the first 100 participants cannot come in the last few days prior to the appointment).
3. Calls will be made until 110 individuals agree to participate.

4. Selected participants will be contacted by telephone 4 weeks prior to the study to set up appointments at a convenient location.
5. Two days prior to the appointment, telephone appointment reminder calls will be made.
6. Because of concern and interest about chemical exposure, a relatively high response rate of ~50% is expected in East Liverpool.

STUDY PROCEDURES

1. The above recruitment methods will be followed.

2. Examiners will meet the day prior to testing and set up testing areas, review all test administrations and set up stations and offices where consent forms, interviews, and tests will be administered.

3. At the time the study will begin, scheduled study participants in groups (three groups per day) of 11 people (+ 1 extra person on one of the days) will be seated in a common area and greeted by the P.I. who will give a brief introduction about the study, the procedures, and the consent form.

4. The P.I. will interview all of the participants with a brief, somewhat structured interview schedule, asking participants about special concerns, fears and observations related to their exposure. The check-out staff person will at this time collect and de-identify the participant's list of current medications, (copied each night at the conclusions of testing) which will be hand-carried in carry-on luggage by the P.I.

5. Trained examiners will introduce themselves to participants and will explain the consent form in detail. Participants will be given time to ask questions. Then two copies of the informed consent will be signed; one for the participant and one for the researcher.

6. The participant will be invited to accompany one of the testers to a private room for testing. The neuropsychological testing will be conducted without any identifiers on the test protocols other than the respective I.D. number. Examiners will be two neuropsychologists and six graduate students in psychology, who will be trained by the P.I. and senior staff (all have completed the course for the protection of human subjects – certificates enclosed).

7. After completion of the tests, the study staff will introduce participants to the certified phlebotomist, who will draw from each participant a total of 12 mL of venous blood (2 tubes of 6 mL) for analysis. Presumably, one needle stick per participant (or as few as needed) will be used by the certified phlebotomist. The Centers for Disease Control and Prevention (CDC) Environmental Health Laboratory has agreed to perform on the first 6-mL tube of whole blood to analyse the Mn, Pb, Cd, and Hg concentrations. The second 6-mL tube will be centrifuged at 800 x g for 10 min at room temperature to separate the serum for the determination of ferritin levels and ALT and GGT activities by the U.S. EPA NHEERL Core laboratories. A total of 200 6-mL whole blood samples will thus be collected. Whole blood will be kept at 4°C and serum samples will be immediately stored at -18°C until analysis and sent weekly by Express Mail to the laboratory. Half a milliliter of serum is needed for the analysis of ferritin concentrations by immunoturbidity using the Roche Tina-quant assay on the Hitachi 912 clinical analyzer. Also half a milliliter of serum is needed to analyse the activities of the liver enzymes ALT and GGT with a Beckman Synchron LX20 using an enzymic rate method. The usual QA/QC methods of the CDC Laboratory will be applied. Each analytic run is surrounded by at least two levels of bench quality control and one blind quality control

sample is inserted with each run (40-60 samples). The methods are CLIA-certified and multiple PT are run, as available. The DLS QA/QC system (Caudill et al., 2008) is referred to as the Multi-Rule Quality Control System (MRQCS). The CDC rules are similar in nomenclature to Westgard's format, but the rules are not identical. Some of the additional features of MRQCS include the ability to distinguish between within-run and among-run precision, accommodating variable numbers of QC measurements per run and accommodating variable numbers of QC samples per pool. Quality control measures include analysis of initial calibration verification standard (National Institute of Standard and Technology standard reference material (NIST SRM) 1643e (trace elements in water, Gaithersburg, MD), a solution of NIST traceable 1 ng ml^{-1} manganese standard as the continuous calibration verification standard, procedural blank and Certified Reference material GBW 07601 (human hair) (Institute of Geophysical and Geochemical Exploration, Langfang, China) will be used as the quality control sample. Results will be given as the average of five replicate measurements of the instrument. Recovery of the analysis of QC standard by this procedure is 90% -110% and, precision is given as %RSD (SD*100/Mean) and for hair samples it varied from 1%-25%.

8. Hair samples will be collected using the following procedures: The collector will first evaluate the presence of sufficient hair on head for collection. Approx. 1-3 cm of hair should be available for collection. The scissors will be cleaned with an alcohol swab in front of the participant. Hair will be cut as close to the skull as possible from the base of the skull near the point halfway between the spine & ear (lower right or left quadrant). When enough mass is an issue, typically on men, smaller snips of hair will be taken in a random pattern. The side of hair sample that was close to the scalp will be marked by tying that end off with sewing thread and the collected hair will be placed into a small envelope with the participant's id clearly indicated. All small envelopes will be sealed and placed into a container and sent to the laboratory for analysis.
9. Toenail samples will be collected in the following manner: A pair of nail clippers will be rubbed with alcohol swabs to be thoroughly cleaned between people. Participants will be asked to clip their nails from all ten toes onto a clean paper (to make it easier to catch all the clippings) and place the collected nails in a small envelope labeled with their respective ID. All small envelopes will be placed into a container and send to the laboratory for analysis.

   Whole sample (Hair/Toenails) will be pre-cleaned with 1% Triton X-100 solution prior to analysis to remove extraneous contaminants. Samples will be acid digested using ultra pure nitric acid at room temperature for 24 hours. Diluted samples will be analyzed for manganese using inductively coupled plasma mass spectrometry (ICP-MS, DRC-II, Perkin Elmer, Norwark, CT) using indium as the internal standard.
10. Two post-baccalaureate level students who were also part of the testing team in Marietta and Mt. Vernon, OH, will conduct check-in and check-out and review the questionnaires and individual participant folders to ascertain that all tests have been completed before the participant leaves. This protocol completeness review will be performed in order to detect unintentional omissions. Participants will at no time be pressured to answer any items they choose not to answer.
11. Upon completion of the study, a gift card for $50.00 for a local store will be presented to each participant as a token of appreciation for participation in the study.
12. Feedback of the group's results will be given to the community and all interested parties either in person or in written form during late summer of 2012. If additional funding

becomes available, the P.I. will also present group results of the study in a community meeting in East Liverpool.

13. After the conclusion of the study, a brief feedback report will be prepared and mailed to each participant reporting the individual's test scores (by domain of function) and results of biomarker analyses. This report will also indicate whether the test results were:
    a) within the normal range
    b) of concern, needing a referral to the family physician for further assessment by specialists as indicated.
14. All relevant professional parties and city officials will be contacted and given feedback of the group's findings.
15. All inquiries by the media will be answered by the team of investigators including the P.I., Mr. Greg Stein from ODH and Dr. George Bollweg, representing the Regional U.S. EPA. Prior to any release of data, results and talking points will have been presented to the entire group of investigators, collaborators and advisory board for input and final wording.

Research details

- The proposed study will take place in rented facilities at locations convenient for participants in East Liverpool, Ohio (the Motor Lodge hotel). The P.I. has made sure that they offer the privacy needed for conducting the study procedures.
- Each participant will be engaged in the study procedures for an average of 2.5 to 4.0 hours.
- It is expected that the brief introduction to the study by the P.I. and consent procedure will take no longer than 10 minutes since participants will already have received detailed information in the recruitment letters. Participants will be engaged in filling out questionnaires for approximately 50 minutes, following which they will have a brief interview by the P.I. for about 10 minutes. The administration of the neuropsychological test battery is expected to take approximately 90 minutes. The administration of the CATSYS is expected to take 10 minutes. The neurological examination (UPDRS) will last 15 minutes. Participants will then have refreshments for about 10 minutes before being introduced to the certified phlebotomist for the drawing of the blood and hair sample collection, followed by the collection of toenail clippings by participants, which will each take 10 minutes.

4. RESEARCH RISKS

- Drawing venous blood from the arm may cause minimal pain when the needle is inserted. There is also a slight risk of bruising and infection where the needle punctures the skin. In rare cases, some people may experience lightheadedness, nausea, or fainting. The certified phlebotomist is trained in recognizing and dealing with these types of reactions. All possible accommodations will be made should this occur. Cutting a small amount of hair will be done with a blunted scissors which will prevent any accidental injuries. Blood samples will also be marked with an ID number only to ensure those analyzing the blood/serum are blinded to the identity of the participant. Arrangements will be made with a local physician on call, who will be recruited by a local colleague practicing in East Liverpool. The pager number and location of this local physician will be obtained so he/she may be contacted and available to address any medical emergency that may arise.

Although such emergencies are highly unlikely, a participant, if necessary can be brought to the nearest Emergency Room at the local hospital.

- There is a risk of experiencing slight fatigue during testing. Testers are trained to look for signs of fatigue and a break will promptly be offered. The participants will also be informed that they can take a break or discontinue testing at any point.
- Participation may involve potential loss of privacy. To minimize this, results will be stored in a password-protected computer database with no identifying information attached. Hard copy files of all of the data will be kept by the P.I. in a locked file cabinet for 5 years with documents containing ID numbers only. Any documents or computer files linking ID numbers to names will be kept in a separate, locked file cabinet (or computer database) only accessible by the P.I. and will also be destroyed after 5 years.

5. CONFIDENTIALITY

All test results will be linked to an ID number, with all personally identifying participant information removed. Results will be stored in an encrypted document on a password-protected computer and all paper materials will be stored in a locked file cabinet in Dr. Bowler's research office laboratory at 8371 Kent Drive, El Cerrito, CA 94530. Only Dr. Bowler will have access to information linking ID numbers and the identities of the participants. Each page in the participant's folder will be coded with an ID number only.

Security will be maintained by having an alarm system in the building and by having each staff member sign a special Data Contract to maintain confidentiality of the data, refraining from any public conversations about the participants. The data will not be released unless subpoenaed by a court of law. Anyone working on the data will also be required to sign this, guaranteeing confidentiality and guaranteeing that these data will not be used unless the P.I. is involved in order to guarantee privacy to the information given by the participant. All data will be maintained for approximately 5 years in hard copy, limiting access to only authorized individuals. The electronic data will be securely stored indefinitely. Unauthorized access will be reported to the relevant parties (IRB, participants, stakeholders). Electronic data will be saved on a device that has the appropriate security safeguards, such as unique identification of authorized users, password protection, automated operating system patch (bug fix) management, anti-virus controls, firewall configuration, and scheduled and automatic backups to protect against data loss.

6. BENEFITS

Participants will receive the test results in writing, which they can send to their physician. We will indicate whether any results are of concern. If abnormalities are found, they will be referred to your family physician.

7. PAYMENT

Upon completion of the study, a gift card for $50.00 from a local store will be presented to each participant as a token of appreciation for participation in the study.

8. COSTS

There is no cost for taking part in the study, aside from the transportation costs of coming to the appointment. Transportation costs involved in coming to the facility, which will be selected to be convenient for participants, will not be reimbursed. The researchers, research

team and sponsors of this project will not provide medical care nor cover the cost of medical care for participants.

9. ALTERNATIVES

The alternative is not to participate in the research.

10. CONSENT/ASSENT PROCESS AND DOCUMENTATION OF CONSENT

a. The study will first be introduced to East Liverpool residents at the community meeting that will take place **on September 15, 2011**. A slide show detailing the study procedures for the community residents will be presented. Residents will be informed that they might receive a letter from the P.I. containing the study description. If selected, residents will be asked to complete and return a stamped, self-addressed card indicating willingness or non-willingness to participate to the P.I. Participants will be able to have their questions answered during the recruitment and screening calls, as well as later, at the time of the appointment. They will be able to ask the P.I. any additional questions that may arise either on site after the meeting or over the telephone when they are administered the inclusion/exclusion questionnaire. They also will be provided additional time to ask questions when the IRB approved consent forms are explained and reviewed by the examiners with each participant at the time of testing. The consent forms will be kept in each participant's testing protocol folder for the duration of the study procedure. Upon arrival at the P.I.'s office, the consent forms will be removed from the folders containing the participants' test protocols and will be in possession of the P.I. , along with the list connecting IDs and names. These forms will be kept in a locked file cabinet in the P.I.'s office.

b. Participants will receive a signed copy of the consent form.

c. The joint consent form approved by SFSU, UNC and ODH was developed and is included. The major change is that blood will no longer be stored as it was in the earlier Marietta study and no signature to allow this is included any longer.

11. INVESTIGATORS' QUALIFICATIONS

All investigators and trained examiners/psychometricians hold valid NIH Ethics Certificates and will follow the usual confidentiality rules. They will not have names of the participants on their protocol they may score and review. The following are the team of experts conducting the study:
a. **Professor Rosemarie Bowler** is a licensed neuropsychologist, qualified medical evaluator, and an emerita lecturer at SFSU. She has published numerous research articles on neurotoxicants and their effects on health. She has previously been on the committee at the National Academy of Science, Institute of Medicine and has served on the CDC/ATSDR Board of Scientific Counselors. She has taught at SFSU since 1977, recently retired, but is still teaching, training and supervising SFSU Psychology graduate students, as well as Ph.D. students in other universities. Professor Bowler has conducted numerous studies of neurotoxicity in adults and has also been responsible for 5 major epidemiologic studies of the effect of neurotoxicants on children (in California, Ohio, France and New Mexico). She has served on numerous committees and boards regarding the chemical effects of exposures on human populations.

Dr. Danelle Lobdell, an epidemiologist from the USEPA at Chapel Hill, NC, is the technical advisor on the project. She will give input on aspects of exposure, selection, statistical analyses and general communications with the community, federal, state and local agencies, and community and scientific presentations. She will be a co-author on manuscripts.

Dr. Harry Roels, Université catholique de Louvain (UCL), Brussels, Belgium. Professor Roels has a long history of scientific work with human populations exposed to neurotoxicants. Professor Roels is one of the most well-known scientific experts on Mn, in fact his study of battery workers in Belgium resulted in the lowering of the Threshold Limit Values (TLVs) of Mn. Dr. Roels is a sought out international expert on Mn and is on many international federal committees on scientific issues related to Mn. He will work closely with the P.I. on all neurotoxicologic and epidemiologic areas of the study and be a co-author on all manuscripts.

Dr. Michelle Colledge, Environmental Health scientist, Division of Regional Operations for Region 5 of the US EPA and ATSDR, conducted the health consultation detailing Mn exposure in EL for almost 9 years. She authored the East Liverpool Air Quality Report, November 16, 2010. Dr. Colledge will assist the P.I. and Dr. Roels on all aspects of selection of the area to be studied, air exposures, the design of analyses using the air data and the analyses of potential relationships between the neurological, neuropsychological and health data and Mn exposure. She will be a co-author on all papers.

Dr. Yangho Kim-Department of Occupational and Environmental Medicine, Ulsan University Hospital, College of Medicine, South Korea. Dr. Kim has previously conducted the neurological examinations using the UPDRS in the Marietta and Mt. Vernon studies and has submitted a manuscript on these findings. He will again administer the UPDRS to all participants in EL and likely will author manuscripts with the research team on the results of the neurological function in EL, comparing the results to normative data and to the data collected from his examinations of residents in Marietta, OH and Mt. Vernon, OH.

Dr. George Bollweg, US EPA Region 5, environmental health scientist, will assist the P.I. and study team on issues of exposure to Mn and other substances. He is a collaborator and will give input on all issues related to Mn exposure in air and biomarkers. He will be a co-author on manuscripts and facilitate communication with the public and the Region.

Mr. Greg Stein, (ODH), community involvement and health education coordinator, will assist the P.I. with community involvement and communications and media related activities. He will assist with the production of media materials and community friendly fact sheets announcing the study, giving results and feedback of the study and also will assist with the health effects results of the study and communication to participants and stake holders. He will be co-author on manuscripts describing the overall study, methods and results.

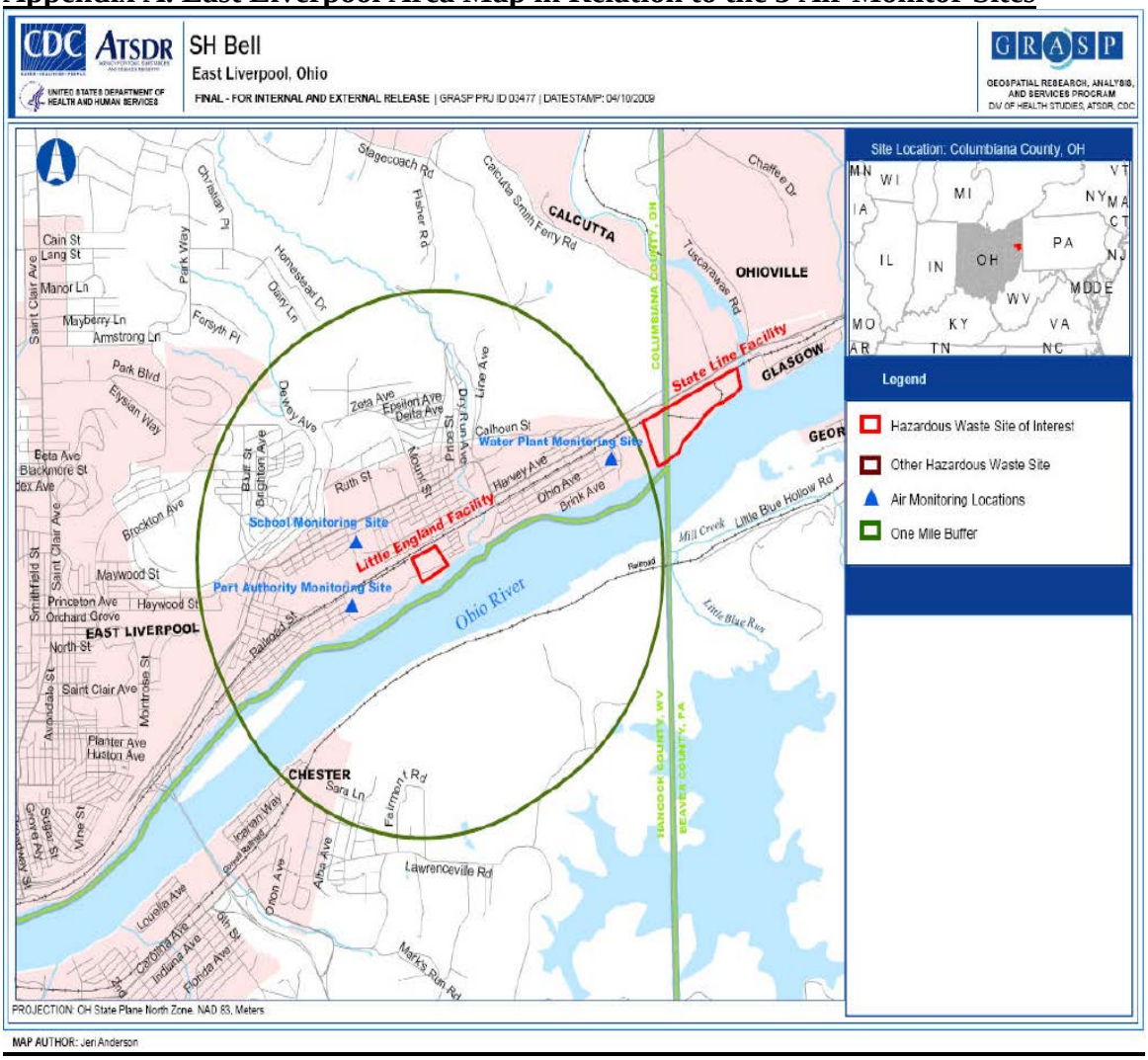
Trained examiners/psychometricians:
Vihra Gocheva, MA (pending, San Francisco State University)
Matthew Harris, MA, Ph.D. (pending, Alliant International University)
Linda Mora, Ph.D., Oakland Children's Hospital
Katherine Wilson, MA, Ph.D. (pending, Alliant International University)

Beth Stutzman, MA, Psy.D. (pending, The Wright Institute)
Matthew Beristianos, MA, Ph.D. (pending, Alliant International University)
Katherine Brown, Psy.D. (pending, Alliant International University)
CATSYS administrator - Ralph Rasalan, MA (pending, San Francisco State University)
2 trained psychology students-TBA
1-2 additional trained data-entry persons from psychology research classes at SFSU

12. FUNDING SOURCES

Funding by the USEPA is awarded as a contract from July 20, 2011 to July 19, 2012. The study will commence immediately once final approval is given, and testing will take place on November 3, 4, 5, and 6, 2011. The main contact person responsible for communication of the cooperative at the U.S. EPA is Dr. Edward Hudgens from the U.S. EPA. Dr. Danelle Lobdell is the technical advisor at the National Health and Environmental Effects Research Laboratory in Chapel Hill, NC. The contact person for EPA at Region 5 is Dr. George Bollweg. Funds will be processed through the Office of Research and Sponsored Programs (ORSP) at SFSU. No conflict of interest exists for any of the researchers.

Appendix A. East Liverpool Area Map in Relation to the 3 Air Monitor Sites



Appendix B. East Liverpool Test Battery

I. NEUROPSYCHOLOGICAL BATTERY (120 MIN)

A. Cognitive (90 min):

1. Animal Naming
2. Digit Symbol Coding
3. Rey-O Copy
4. Digit Span
5. Rey-O Immediate
6. ACT
7. Stroop Color Word Test
8. Trails A & B
9. Similarities
10. Rey-O delayed
11. NAB Memory
12. REY-15
13. Victoria Symptom Validity (if needed, based on Rey-15 scores)

B. Motor & Tremor :

- CATSYS
- Grooved Pegboard
- Fingertapping
- Dynamometer
- Parallel lines

C. UPDRS – ADL and Motor (15 minutes)

D. Mood:

- SCL 90-R
- BRFSS
- Satisfaction with life Scale
- Environmental Worry Scale (EWS)

II. SELF-REPORT QUESTIONNAIRES

- Health Questionnaire

III. BIOMARKERS & AIR MEASUREMENTS

A. Blood:

- Mn, Pb, Hg, Cd

B. Hair

Mn

C. Toenails:

- Mn -10 toenail clippings

D. Serum:

- Ferritin

Test Battery Details

Cognitive Tests *(In alphabetical order)*

Animal Naming (Lezak et al., 2004)*:*

A category fluency test, requiring the naming of as many animals as possible in 1 minute.

Auditory Consonant Trigrams (ACT) (Lezak et al., 2004):

A test of divided attention and concentration in which participants are orally presented with 3 consonant letters and a specified number from which they are asked to count backwards by three for 3, 9, or 18 seconds, at which point counting is interrupted and they have to recall the 3 consonants.

Neuropsychological Assessment Battery (NAB): Memory Module (Stern and White, 2003):

A test with high ecological validity consisting of an array of subtests assessing learning and memory. Subtests include: list learning, shape learning, story learning and daily living memory with immediate and delayed recognition trials and forced-choice recognition.

Rey-Osterrieth Complex Figure Test (Meyers and Meyers, 1995)*:*

Assesses planning, organizational skills and problem-solving strategies and perceptual, motor and memory functions. To assess visuospatial constructional ability and visuospatial memory participants are asked to copy a complex figure and then to reproduce it after a 3 and 30 minute delay. It has been shown sensitive in Parkinson's disease and frontal lobe damage.

Stroop Color and Word Test (Golden, 1978)*:*

Measures the ease with which a person can shift his/her perceptual set to conform to changing demands and suppress a habitual response in favor of an unusual one. The test involves word reading, color naming, and set shifting (reading color names printed in a different color ink) and is sensitive to dementia, depression, PD, schizophrenia, Huntigton's disease, and head injury. Color-blind subjects are excluded.

Trail Making Tests (TMT) (Strauss et al., 2006)*:*

Tests of speed of attention, sequencing, mental flexibility, visual search and motor function. It requires connecting in order encircled numbers or letters, randomly arranged on a page. Part A requires the connection of numbers in order, and part *B r*equires the sequencing of numbers and letters in alternating ascending order.

Wechsler Adult Intelligence Scale-Third Edition (WAIS-III) Subtests *(Wechsler, 1997)*:

Digit Span (3 min) – a measure of attention and sustaining concentration

***Digit Symbol (3 min*) –** a spatial measure involving learning and speed

***Similarities* (*10 min*)** – higher level verbal abstraction and reasoning, will also be used as an estimate of premorbid function

Mood and Health Questionnaires

Environmental Worry Scale (EWS) (Bowler and Schwarzer, 1991)

This scale is a 17-item measure developed to predict intention to avoid chemicals and has satisfactory psychometric properties. A 5-item version was used in this study to examine participants' particular concerns about chemical exposures, which is also has satisfactory normative properties.

Health-Related Quality of Life Scale (BRFSS)(Centers for Disease Control and Prevention)

This scale is a brief 4-item scale developed by the Centers for Disease Control and Prevention to assess self-perceived recent health, recent mental health and activity limitations. Nationwide normative data is available.

Satisfaction with Life Scale (Diener et al., 1985)

This 5-item scale is a brief measure of life satisfaction. It asks participants to compare the current status of their life to their self-defined expectations of how they would like their lives to be. It has satisfactory psychometric properties.

Symptom Checklist-90-Revised (SCL-90-R) (Derogatis, 1992)

A 90-item standardized scale asking participants to rate how much of a problem certain symptoms had been in the prior week, using a five-point scale. Domains/scales are: Somatization, Obsessive-Compulsive, Interpersonal Sensitivity, Depression, Anxiety, Hostility, Phobic Anxiety, Paranoid Ideation, Psychoticism, and summary indices.

General Health questionnaire:

A health questionnaire will be administered in a printed format. It will include socio-demographic information, smoking and drinking habits, hobbies with exposure to neurotoxic substances (gardening using pesticides, solvents, painting, welding etc), a history of illnesses and familial illnesses (with emphasis on neurological disorders), accidents and current symptoms (sleep, respiratory, cardiovascular, musculo-skeletal, neurologic and neuropsychiatric).

Tests of Effort

Victoria Symptom Validity Test (VSVT) *(Slick et al., 2005)*

This computerized test is used to assess effort on memory tests and memory complaints exaggeration. The VSVT includes the presentation of 48 five-digit numbers and the forced-choice delayed identification of that number. Protocols where the number of correct items is above chance (50%) are considered valid. (15 minutes).

Rey's 15-Item Visual Memory Test (Strauss et al., 2006)

It consists of a card with 15 printed items (letters, numbers and shapes) arranged in 3 columns and 5 rows. The examinee is told there are 15 different (emphasized) items to remember which are to be reproduced immediately on a blank sheet of paper following a 10-second exposure to the stimulus card. Although it is presented as a difficult task, it is actually quite simple because there is redundancy among items that reduces the amount of information to be remembered (i.e. three main ideas). It is used to test motivation and potential deficit exaggeration.

Neurological examination

The motor/movement components and activities of daily living of the Unified Parkinson's disease Rating Scale (UPDRS) will be administered. The UPDRS is the most widely used scale for evaluation of clinical impairment in motor function. It contains 27 items, including assessments of posture, gait, postural stability, bradykinesia, and general hand and leg movements and tremor. It has good reliability and validity, utilizing the standardized test methodology and videotaped reference guide developed by (Goetz et al., 2003). It includes the Activities of Daily Living section (UPDRS II) and has 13 items of speech and daily activities and tasks. All items are rated on a scale of 0 (normal) to 3 or 4, depending on the scale with clinical descriptor for each rating ranging from normal to severe.

Movement, Motor and Tremor *(In alphabetical order)*

Computerized Adaptive Testing System (Danish Product Development, 1996)

1) **CATSYS hand tremo**r test. Hand tremor will be measured using the TREMOR 7.0 Test System. Vibrations within each hand are recorded with the TREMOR PEN. A two-axis

micro-accelerometer is embedded within the tip of the 12 cm x 0.8 cm TREMOR PEN, which is connected to a PC data log system. The TREMOR PEN is sensitive to vibrations that occur in a plane perpendicular to the PEN axis. Vibrations will be analyzed using the Fourier Power Spectrum, which plots the normalized power distribution (the relative harmonic contents) of the vibration measurement period in a frequency domain. The Harmonic Index, highly sensitive to abnormal tremor patterns, relates the Fourier Power Spectrum to that of a single harmonic oscillation.

2) **CATSYS postural sway** test. This test of postural stability will be performed in three conditions (35 seconds in each condition) while the participant stands on a 50 cm platform balance plate with a) eyes open , b) eyes closed, and c) eyes closed standing on 2 cm foam. Postural stability is measured in Mean Sway (mean of force center position to all recorded center positions), Transversal Sway (sway movement from side to side), and Sagittal Sway (sway movement back and forth). A Sway Index (in relation to normative age-adjusted data) is computed for each condition.

Fingertapping Test (Lezak et al., 2004)

A measure of bilateral psychomotor speed; The participant is asked to tap a lever as quickly as possible. Scores are the mean of five 10-second trials for each hand.

Grip Strength *(Dynamometer)* (Lezak et al., 2004)

A test of grip strength with two trials administered bilaterally.

Grooved Pegboard Test(Lezak et al., 2004)

Tactile speed and visuomotor coordination; Pegs are inserted in the slots as quickly as possible; pegs have a ridge on one side, requiring a rotation to line them up with the slots. Completion time is recorded for each hand.

Parallel Lines - Graphomotor Tremo*r*(Lezak et al., 2004)

Graphomotor tremor will be assessed by drawing lines as straight as possible within defined 3-inch and 1-inch high boundaries without lifting the pencil from the paper. Qualitative evaluation of tremor by a neuropsychologist with ratings of within normal limits, mild, moderate, or severe.

Appendix C. 2000 US Census Demographic Factors

		East Liverpool	%	Marietta	%	Mount Vernon	%
NO. TOTAL POPULATION		13,089		14,515	--	14,375	--
PLACE OF BIRTH	% US-BORN (UB)	--	99.1	--	98.8	--	98.4
	% OH-BORN (OF UB)	--	74.2	--	66.7	--	81.5
	% FOREIGN-BORN (FB)	--	0.5	--	1.2	--	1.6
	% NON-CITIZEN (OF FB)	--		--	43.2	--	40.7
POVERTY	% BELOW POVERTY	--	25.2	--	16.9	--	15.6
RACE	NO. WHITE	12,153	92.8	13,979	96.3	13,895	96.7
	NO. BLACK	630	4.8	157	1.1	166	1.2
	NO. OTHER	27	0.2	379	2.6	314	2.1
ETHNICITY	NO. HISPANIC	94	0.7	114	0.8	125	0.9
SEX	NO. MALE	6,070	46.4	6,757	46.6	6656	46.3
	NO. FEMALE	7,019	53.6	7,758	53.4	7,719	53.7
AGE	MEDIAN AGE, YEARS	35.7		38.4	--	37.1	--
	MEDIAN AGE MALE			36.1	--	33.9	--
	MEDIAN AGE FEMALE			40.4	--	40.0	--
	NO. 65+ YEARS	2,100	16	2,573	17.7		18.3
	NO. FEMALE 15-45 YEARS (% ♀)			3,330	42.9	3,051	39.5
	NO. PRE-SCHOOL ≤ 5 YEARS			947	6.5	1,171	8.1
	NO. SCHOOL AGE 6-18 YEARS			2,400	16.5	2,429	16.9
	NO. 7-8 YEARS			351	--	406	--
	NO. 9-10 YEARS			325	--	370	--
	NO. 35-65 YEARS			5,412	--	5,075	--
	NO. 25+ YEARS			9,381	64.6	9,504	66.1
EDUCATION (FOR 25+ YRS)	% LESS THAN HIGH SCHOOL	--	26.6	--	15.9	--	19.8
	% HIGH SCHOOL	--	45	--	34.9	--	39.5
	% SOME COLLEGE	--	21.2	--	25.9	--	22.6
	% COLLEGE	--	2.7	--	12.8	--	10.9
	% MORE THAN COLLEGE	--		--	10.4	--	7.2
NO. HOUSING UNITS (HU)		5,728	--	6,609	--	6,713	--

	NO. URBAN			6,426	97.2	6,543	97.5
	NO. RURAL			183	2.8	170	2.5
	% BUILT BEFORE 1970			--	75.5	--	75.0
	MEDIAN YEAR BUILT			1948	--	1952	--
NO. HOUSEHOLDS (HH)				5,904	--	6,187	--
	AVERAGE HH SIZE, PERSONS	2.4	--	2.2	--	2.2	--
	MEDIAN HH INCOME	$23,138	--	$29,272	--	$29,801	--

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CONSENT FORM

San Francisco State University

Informed consent to participate in the following research study:

Relationship of airborne manganese exposure to neurobehavioral and health status of adults

A. PURPOSE AND BACKGROUND

The researcher of this study, Rosemarie Bowler, Ph.D., is a professor emerita of Psychology at San Francisco State University. The purpose of this study is to determine if there are negative health effects from exposure to airborne manganese and other chemicals in adults. You are being invited to participate in this study because you are a long term resident (10 or more years) of East Liverpool, Ohio and between the ages of 30 and 75. Your participation in this study is completely voluntary.

B. PROCEDURES

If you agree to participate, the following will occur:

- All procedures will take place in our field office in East Liverpool.
- You will be interviewed about your health history. The interview will last approximately 15 minutes.
- You will be asked to complete questionnaires on your medical, social, and psychological history. This will take you about 60 minutes.
- You will be given tests used to measure multiple areas of cognitive functioning, such as general intellectual ability, memory, attention, learning, language, and visual and spatial skills. These tests will take no more than 75 minutes.
- Your motor functioning will be examined with tests of hand strength, balance and tremor, and dexterity. These will take approximately 15 minutes to complete.
- 12 mL (about 2 teaspoons) of blood will be drawn from a vein in your arm by a certified phlebotomist (a person trained to collect blood samples). Your blood will be securely shipped to, stored, and analyzed at the Centers for Disease Control and Prevention (CDC) Environmental Health Laboratory under the direction of the assistant chief of the laboratory, Kathleen Caldwell, Ph.D. Your blood will be analyzed for the following compounds: manganese, lead, mercury, and cadmium, in addition to iron and 2 liver enzymes.
- We will ask you to provide small amounts of your hair (a small sample taken from the back of the head underneath other hair so it will not be noticeable) as well as toenail clippings from all 10 toes. These samples will be analyzed in order to evaluate your exposure to metals.
- Your toenail and hair clippings will be securely shipped to, stored, and analyzed at the Harvard School of Public Health Trace Metals Laboratory. Your toenail clippings will be analyzed for levels of metals.
- Your participation in this study will take an average of 2.5 to 4.0 hours.

C. RISKS

1) When blood is drawn, there is a risk of experiencing slight pain or a prick where the needle punctures the skin. There is also a slight risk of bruising or an infection where the needle punctures the skin. In rare cases, some people may experience lightheadedness, nausea, or fainting. The certified phlebotomist is trained in recognizing and dealing with such reactions. A licensed medical doctor (M.D.) will be on call nearby at all times and will give a consultation in case of a medical emergency for appropriate emergency medical care.

2) Participation in research may involve some possibility of loss of privacy. This risk will be reduced to the extent possible. More information about this risk and how we will reduce it appears in the confidentiality section below.

3) You may feel slight fatigue during testing. Should this occur, you can choose to take a break or discontinue testing at any point.

4) Some of the questions in the questionnaires may be personal and sensitive in nature. You are not required to answer a particular question if you feel uncomfortable.

5) It is possible that results from the blood analysis could reveal serious health problems that you are not aware of. After the analysis, you will be given a report indicating all your test results, and if anything serious is found, you are advised to consult with your family doctor or a local healthcare provider.
6) There may be risks and discomforts that are not yet known.
7) The researchers, research team and sponsors of this project will not provide medical care to participants nor will they cover the cost of medical care for participants.

D. WHAT WILL HAPPEN IF YOU ARE INJURED BY THIS RESEARCH?

All forms of medical research, diagnosis, and treatment involve some risk of injury or illness. Despite our high level of precaution, you may develop an injury or illness due to participating in this study. If you develop an injury or illness determined by the on duty physician to be due to your participation in this research, the EPA will reimburse your medical expenses to treat the injury or illness up to $5000. If you believe your injury or illness was due to a lack of reasonable care or other negligent action, you have the right to pursue legal remedy. The Federal Tort Claims Act, 28 U.S.C. 2671 et. seq., provides for money damages against the United Sates when personal injury or property loss results from the negligent or wrongful act or omission of any employee of the EPA while acting within the scope of his or her employment. Signing this consent form does not waive any of your legal rights or release the investigator, the sponsor, the institution, or its agents from liability for negligence. If a research-related injury occurs, you should contact the Director of the EPA NHEERL Human Research Protocol Office at 919-966-6208 or the Office for the Protection of Human Subjects at San Francisco State University, at 415-338-1093 or protocol@sfsu.edu.

E. CONFIDENTIALITY

Your information will be handled confidentially. Your name will not be used in any published reports about this study. Your results will be entered into a computer database without your name or other identifiers. An ID number will be assigned to all of your test results and only Professor Rosemarie Bowler will be aware of your identity and ID number. The data will be handled only by research staff, all of whom will sign a special confidentiality contract, and will be entered in a password-protected computer database. All research records and test results will be stored in locked file cabinets. All electronic data and results will be kept in an encrypted document on a password-protected computer. Your information will not be released unless subpoenaed by a court of law. All data will be maintained for approximately 5 years in hard copy with access limited to only authorized individuals. The electronic data will be securely stored indefinitely. Unauthorized access will be reported to the relevant parties (participants, stakeholders). Electronic data will be saved on a device that has the appropriate security safeguards (password protection, etc).

F. DIRECT BENEFITS

You will receive the test results in writing, which you can send to your physician. We will indicate whether any results are of concern. If abnormalities are found, you will be referred to your family physician.

G. COSTS

There is no cost to you for participating in this research, aside from the transportation costs of coming to the appointment. Transportation costs involved in come to the field office will not be reimbursed. Medical care will not be provided by the researchers or research team nor will medical care costs be covered.

H. COMPENSATION

You will be presented with a $50 gift card, as a token of appreciation for your participation in the study. Early withdrawal from the study or incompletion of major parts of the study will not be compensated monetarily.

I. ALTERNATIVES

The alternative is not to participate in the research.

J. QUESTIONS

You have spoken with Professor Rosemarie Bowler or one of her collaborators about this study and have had your questions answered. If you have any further questions about the study, you may contact the researcher by email at rbowl@sfsu.edu or by phone at 510-236-5599. Questions about your rights as a study participant, or comments or complaints about the study also may be addressed to the Office for the Protection of Human Subjects at San Francisco State University, at 415-338-1093 or protocol@sfsu.edu.

K. CONSENT

You have been given a copy of this consent form to keep.

PARTICIPATION IN THIS RESEARCH STUDY IS VOLUNTARY. You are free to decline to participate in this research study. You may withdraw from this study at any point without penalty. Even if you sign, you may stop at any time. Your decision to take part in this research will have no influence on your present or future status at San Francisco State University.

Name _____

Signature _____ Date November___, 2011
Participant

Signature _____ Date November 3, 2011
Rosemarie M. Bowler, Ph.D.

Standard Operating Procedures (SOP) for testing

Dr. Rosemarie Bowler
San Francisco State University

An Epidemiologic Health Study of Manganese Exposure in adult residents of East Liverpool, Ohio

Standard Operating Procedure

Data Collection / Testing Participants

Update Date: August 24th, 2011

Review Date: September 30, 2011

Reviewed and Approved by: Rosemarie Bowler

Testing procedure for participants

1.0 Purpose

This standard operating procedure (SOP) describes the data collection process which will be used to collect data from participants during the health study of East Liverpool, Ohio.

2.0 Personnel

Project investigators and staff will administer tests and perform check-in and check-out. All investigators and staff have completed the NIH training course for the protection of human research participants and the certificates are enclosed.
Blood samples will be a collected by a licensed phlebotomist and hair and toenail samples will be collected by the neurotoxichologist in the project.
Conducting neurological examinations (UPDRS) and conducting reviews of medical history will be a trained and licensed physician, Dr. Yangho Kim.

3.0 Procedure

CHECK-IN

Participants will enter the hotel (the East Liverpool Motor Lodge) and meet at the conference room, where they will check-in.

The check-in staff will have a printed appointment sheet which contains the names of the participants to be tested that day. Each participant will receive a testing folder with a unique randomly assigned ID. This randomly-assigned ID number will be the identifying information for the participant for the rest of the study. The folder will contain all the test protocols, a testing checklist. All testing protocols will be pre-stamped with the ID numbers. Participants will also be handed a stack of index cards corresponding to each station they must visit before they are finished with their participation. The check-in staff will write in the ID next to the corresponding name on the appointment checklist. Participants will be asked to be seated and to begin to read the Consent form. The P.I. will give a brief talk, welcoming the participants and explaining the process of testing and the testing stations which are described below. Before any testing begins, the consent form will have been signed voluntarily by the participant and witnessed by the P.I. or staff members who will also sign the consent form. The participants will be informed that the P.I. will be available for any difficulties which may arise. Additionally, the seven trained neuropsychological testers will also communicate directly with the P.I., who will be available throughout the study, if any unexpected problems or difficulties arise. Appropriate telephone numbers and telephone numbers for hospital emergencies will be available to the P.I. and the staff should they be needed.

Following the consent procedures, participants will be accompanied by one of the testers to a particular testing station. The various stations are described below.

At each station, particular tests will be administered. In the case of the Questionnaire station, this will be the "home base" room where all participants return between testing stations. There will be 2 staff members in the questionnaire/check-in and check-out room who will assist and direct the participants to their next testing station or task. When each set of tests is completed, the tester will take the index card corresponding to their station, and initial the checklist on the inside of the participant's test folder indicating that they have completed the respective testing station. Staff will return the participant to the conference room after testing and will help instruct them where to go next.

QUESTIONNAIRE STATION

Check-in staff will instruct participants to fill their packet of questionnaires while they are waiting for a tester who will identify that the participant still needs to complete testing at their station based on their color-coded cards laid out in front of each participant. Questionnaires include the health questionnaire, environmental worry scale, BRFSS, satisfaction with life, and the SCL-90-R. When a participant has completed all of their questionnaires, check-in/check-out staff will collect their QUESTIONNAIRE index card.

COGNITIVE TEST STATION

Advanced level trained testers will be conducting the neuropsychological testing. The neuropsychological tester will collect the participant from the conference room and examine their folder and their index cards to ensure that they have not yet completed neuropsychological testing. The tester will escort the participant to the appropriate hotel room for testing. All neuropsychological tests will be in a separate subfolder in the participant's main folder. This folder will be already numbered and all ID-stamped test protocols will be contained in this folder. The neuropsychological tester will hold on to this testing folder and score the respective tests sufficiently so that the later data scorers will be able to complete the summary scoring. They will, however, return the test folder at the end of EACH testing day to the main check-in/check-out station, where the ID stamped folders are maintained. The tests will be administered in the order indicated in the *Test Checklist,* stapled to teach participant's test folder.

Each test will be administered following the procedures outlined in the instructions in the test's administration manual. The relevant administration instructions are included in a folder each tester will have.

MOTOR TEST STATION

A staff member trained to conduct motor testing will approach the participant in the conference room, and examine their folder to ensure that they still have their MOTOR STATION index card, indicating that they have not received motor testing. They will administer the motor tests from the MOTOR section of the *Test Checklist*, in that order, in the conference room.

Each test will be administered following the procedures outlined in the instructions in the test's administration manual.

BLOOD COLLECTION STATION

A certified phlebotomist will be collecting blood samples from participants. They will approach the participants from the conference room, and take them to a room where the blood collections will be done. They will examine their folder to ensure that they still have their BLOOD STATION index card, indicating that they have not given their blood sample yet. They will conduct this following the blood collection procedure outlined on the document *"CDC Study 2009-0013 EPA Manganese Study"* which outlines the procedure for blood collection, processing, and shipping for analysis. This will be done while observing Universal Precautions as defined in the *OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030).*

The participants will be offered a snack and coffee or lemonade afterwards which will be available in the check-in/check-out room

Dr. Harry Roels, a biochemist, will be assisting the phlebotomist in making sure each vial of blood will have the appropriate ID label affixed safely. Dr. Roels will then process the second tube of blood for obtaining serum after 2 hours of coagulation and subsequent centrifugation. The serum will be transferred to a 5 ml Nalgene cryovial and be appropriately identified. The blood will be stored in the mailing box in a refrigerator at the Motor Lodge hotel. Serum will be frozen immediately and kept at a temperature as described in the blood protocol below. Whole blood (chilled with blue ice packs) will be shipped by Fedex overnight to the CDC Laboratory for analysis of manganese, lead, cadmium, and mercury and the frozen serum will be shipped to the EPA laboratory for analyses of ferritin.

HAIR AND TOENAILS STATION

Dr. Harry Roels will also be in charge of the hair collection procedures. He will first evaluate the presence of sufficient hair on head for collection. Approx. 1-3 cm of hair should be available for collection. The scissors will be cleaned with an alcohol swab in front of the participant. Hair will be cut as close to the skull as possible from the base of the skull near the point halfway between the spine & ear (lower right or left quadrant). When enough mass is an issue, typically on men, smaller snips of hair will be taken in a random pattern. The side of hair sample that was close to the scalp will be marked by tying that end off with sewing thread and the collected hair will be placed into a small envelope with the participant's id clearly indicated. All small envelopes will be sealed and placed into a container and sent to the laboratory for analysis.

Toenail samples will be collected in the following manner: A pair of nail clippers will be rubbed with alcohol swabs to be thoroughly cleaned between people. Participants will be asked to clip their nails from all ten toes onto a clean paper (to make it easier to catch all the clippings) and place the collected nails in a small envelope labeled with their respective ID. All small envelopes will be placed into a container and send to the laboratory for analysis.

CATSYS STATION

Participants will be collected from the conference room and invited to a room where the CATSYS information will be collected. The examiner will check the participant's folder to ensure that they still have their CATSYS STATION index card, indicating that they have not yet performed this test. The CATSYS will be administered according to the standardized procedures published in the CATSYS administration manual.

UPDRS STATION

Dr. Yangho Kim, a licensed physician, will conduct the UPDRS, a neurological examination which tests for signs of parkinsonism. He, or a staff person, will collect the participant from the conference room, and take them to a room where the examination will be done. They will examine their folder to ensure that they still have their small UPDRS STATION index card, indicating that they have not yet performed this test. The motor scale and ADL sections will be used for the purpose of this study, which are published by the Movement Disorder Association, and enclosed in this QA packet as "*UPDRS numbered"*.

CHECK-OUT

Once the participant has completed the tests at each station, all of their index cards (except for the MEDICAL HISTORY card) will have been collected by staff and their checklist will be all marked off (except for check-out). At this point, they will report to the main desk in the conference room. When checking out, staff will review the questionnaires for completion and if there are any notable discrepancies, they will instruct the participant to wait, and will call the physician, Yangho Kim, to clarify any part of their MEDICAL HISTORY from the participant. When completed, the participant will be returned to the front desk, where the staff will perform the final check-out. Staff will sign out the participant on their list and award the participant with their gift certificate for completion of the study. Participants will be asked to fill out a receipt indicating that they have been presented with a $50 giftcard for participating in the study.

MEDICAL HISTORY

This will be done by self-report with any partial or incomplete medical problem reviewed by a licensed physician, Dr. Yango Kim, as outlined in the IRB proposal. The Health Questionnaire, symptoms, illnesses, and medications, with specific emphasis on any potential manganese-related items will be carefully checked.

4.0 Testing and Validation from Quality Assurance (QA)

All activities will be overseen by the primary investigator, Dr. Rosemarie Bowler. She will observe testing and other procedures to ensure that they are being conducted in accordance with the outlined operating procedures.

An *Incident Log* will be maintained to note any events which occur that are outside of the planned operating procedures.

Blood Collection Procedure

Blood Collection Procedure

NOTE: Universal Precautions should be observed as defined in the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030).

Analytes to be measured in this study:

- **Manganese, lead, cadmium, and mercury in whole blood, sent to the CDC lab**
- **Ferritin in serum, sent to EPA lab**

Blood will be collected using a 21-g or 23-g butterfly needle attached to a Vacutainer™ (Becton-Dickinson, Rutherford, NJ) disposable one-time use plastic needle holder. One 3 mL draw purple (lavender) top tube and one 7 ml SST should be collected for all of the testing that will be done at the Division of Laboratory Sciences, CDC. The following items will be used for specimen collection, processing and/or shipping. Some items are provided by CDC and others will be provided at the site of collection:

- Disposable gloves in several sizes
- Plastic-lined absorbent pads (to provide a clean work surface)
- Disposable tourniquets
- Vacutainer™ needle holder (clear plastic barrel)
- 21-g/23-g butterfly needle with attached tubing, (or, 21-g Vacutainer™ needle [regular straight needle] - no tubing)
- Alcohol pads
- Sterile gauze
- Adhesive bandages
- One 3-mL draw (EDTA) purple top Vacutainer™ or Monoject™ tube for whole blood
- One 7-ml draw SST (contains a gel separator) gold or tiger top tube for serum collection
- One 5-ml Nalgene cryovial for serum storage if processing is done on site
- Sharps disposal container
- Bar-coded specimen ID labels for collection tubes
- Saf-T-Pak™ 95kPa Tyvek® shipping bags with gel absorbent strips or zip lock bags
- Disposable plastic transfer pipet (sterile, individually wrapped) if processing is done on site
- Cardboard specimen storage boxes for each specimen type (9x9 for Purple top tubes), (10x10 for 5 ml cryovials) or 2-part 5 tube styrofoam holder with cardboard sleeve.
- Package sealing tape
- -20 °C (or lower) freezer for temporary storage of serum and urine vials
- Centrifuge capable of attaining force of 1000 x g
- Dry ice for shipping frozen specimens
- Pre-frozen ice packs for shipping Purple top tubes or unprocessed SST tubes

BLOOD COLLECTION PROCEDURE:

Phlebotomy: Blood collection will be performed only by experienced phlebotomists. These instructions are for reference only and are in no way intended to instruct how to collect blood by anyone who has no previous experience.
The phlebotomist will do the following:

- Apply the tourniquet to the upper arm (approximately 5” above the elbow for adults) Determine the best a vein site for venipuncture by palpating the skin area above the antecubital space (i.e., above the inside of the elbow). Placing the tourniquet high up on the upper arm will help the vein become more evident.
- After a vein has been selected, remove the tourniquet, and cleanse the antecubital space vein site with an alcohol pad. Allow the skin to air dry, or pat it dry with a sterile gauze pad. Place the

tourniquet on the arm again and locate the selected vein. Insert the needle with its bevel, or cut side, facing upward, and secure it in place with an adhesive bandage.

- Collect one Purple top tube first and one SST tube on each participant (mix well after collection) .
- Allow all tubes to fill to the stated volume on the tube (the Purple top tube will fill about 2/3 of the total volume since it is engineered to draw only 3 mls). The small amount of air that is present in the tubing of the butterfly needle apparatus will cause the volume of blood collected to be reduced by 0.5 mL in the first tube collected.
- After the SST tube has been removed from the needle holder, remove the needle in a swift and smooth motion, and apply pressure with a gauze pad to the venipuncture site. Have the participant apply pressure over the gauze for about 5 minutes with the arm extended overhead.
- Label each tube with the provided bar-coded participant ID.

SPECIMEN PROCESSING INSTRUCTIONS

To be performed by Dr. Harry Roels

- The Purple top tube will be labeled and placed in the storage box provided for shipping at the end of the study or 5 tube Styrofoam holder (for daily shipments). Refrigerate until shipment to CDC.
- Place the SST tubes in an upright position in a rack after collection, and allow them to clot for at least one hour to ensure that as much serum can be recovered from these tubes after clot retraction and centrifugation. (Two hours is even better, if possible.)
- After the SST tubes have been allowed to clot sufficiently, place the tubes in a centrifuge for 15-20 minutes at a speed of 2400 rpm (do not exceed 3000 rpm), or 1500 x G. If the clot appears to be adhered to the top of the stopper, place a piece of sterile gauze over the tube stopper. Slowly and carefully, loosen the stopper until the clot is released and falls back into the glass portion of the tube (placing the tubes upright in a rack soon after collection will prevent the clot from adhering to the stopper). Replace the stopper, taking care not to touch the inside of the stopper or glass tube with your gloved fingers.
- During centrifugation, the gel that was at the bottom of the SST tube will migrate up and over the red cell clot leaving the serum above the gel layer. If it appears that the gel layer is not completely over the red cell clot, centrifuge the tube for an additional 5-10 minutes until it completely covers the red cell clot.
- Once the tubes have been centrifuged and the serum appears over the gel layer with no contact with the red cell clot, the tube can be placed in the refrigerator if further processing is not done to remove the serum. The tube may be shipped to CDC in the 5 tube Styrofoam holders with the Purple top tube for further processing if not done on site (ship daily). If further processing is done on site, the serum can be poured or pipetted directly into a 5 ml Nalgene cryovial. Label the cryovial with a bar-coded label for Ferritin.

Collection/Shipping Log:

Record the blood collection using the log sheet. Mark each sample that is collected with a (√) and any sample not collected with an (X). Any comments concerning the specimen collection should be annotated in the spaces provided. A copy of this log will be sent with the shipment.

Shipping Instructions (for samples that CANNOT be processed on site):

After blood is centrifuged to obtain serum for analyses of ferritin, the serum samples will be stored immediately in the freezer compartment of a refrigerator and kept there for no longer than 72 hours. All serum samples will be packed in dry ice for overnight shipping through Federal Express from East Liverpool to the EPA lab.

Purple Top Tubes AND SST Tubes:

If there is no one to process the SST tubes, all of the tubes collected in a single day should be packaged in Styrofoam tube holders. These will hold 5 tubes each. All of the Purple top tubes may be packaged together and all of the SST tubes packaged separately together from the Purple top tubes. Place each

Styrofoam tube holder in one of the cardboard boxes with the red stripes. Several of these boxes may be placed in the Saf-T-Pak bags sets or zip bags. Place the sealed bags containing the Purple top tubes and the SST tubes inside a Styrofoam-lined insulated shipping container and add several pre-frozen ice packs along with any extra packing material such as newspaper to fill any voids in the shipping container. Seal the container with packing tape and add a FedEx airbill to the outside. Place a label also for "**EXEMPT HUMAN SPECIMEN**".

If the samples cannot be processed on site, then these need to be shipped daily to CDC.

Call or email the information about the shipment using the numbers and email address below. Any electronic files should be included in the email.

Ship whole blood to the following address:

Charles Dodson
Centers for Disease Control
Building 110, Room 1211
4770 Buford Hwy NE
Chamblee, GA 30341
770.488.4305
wcd1@cdc.gov

EPA Manganese Study
Procedure for Ferritin Samples to the NHEERL

1. Prepare serum samples in 5-mL Nalgene vials as described in the CDC protocol.

2. List all samples to be shipped on the Analytical Chemistry Core chain of custody form. I

3. Place sealed plastic bags containing the 5-mL Nalgene vials inside a Styrofoam-lined insulated shipping container. Place the sample boxes on the bottom of the shipper. Leave room at the top to add 10-12 lb of dry ice. Fill any extra space in the shipper with packing material (newspaper or packing peanuts) to secure the sample boxes.

4. Place a signed copy of the Analytical Chemistry Core chain of custody in a separate sealed plastic bag on top of the packing material. Place the Styrofoam lid on the box. Close the outer cardboard flaps, and tape them securely shut. Place a "**DRY ICE**" label and "**EXEMPT HUMAN SPECIMEN**" label on the outside of this shipper containing dry ice and indicate the amount of dry ice (e.g., 12 lb) on the label and the air bill and affix to the outside of the container.

5. E-mail an electronic copy of the chain of custody and the shipping date to the Judy Richards: richards.judy@epa.gov.

6. Ship overnight to the address below. Note that samples cannot be received on Saturdays. Call Judy Richards, (919) 541-2398, with questions.

    USEPA
    Attn: Judy Richards
    109 TW Alexander Dr
    Chemical Services
    Building A Loading Dock Rm A-184
    RTP, NC 27711

Regulations (Standards - 29 CFR)

Bloodborne pathogens. - 1910.1030

Regulations (Standards - 29 CFR) - Table of Contents

- **Part Number:** 1910
- **Part Title:** Occupational Safety and Health Standards
- **Subpart:** Z
- **Subpart Title:** Toxic and Hazardous Substances
- **Standard Number:** 1910.1030
- **Title:** Bloodborne pathogens.

- **Appendix:** A

1910.1030(a)

Scope and Application. This section applies to all occupational exposure to blood or other potentially infectious materials as defined by paragraph (b) of this section.

1910.1030(b)

Definitions. For purposes of this section, the following shall apply:

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.

Blood means human blood, human blood components, and products made from human blood.

Bloodborne Pathogens means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

Clinical Laboratory means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.

Contaminated means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

Contaminated Laundry means laundry which has been soiled with blood or other potentially infectious materials or may contain sharps.

Contaminated Sharps means any contaminated object that can penetrate the skin

including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

Decontamination means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

Director means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative.

Engineering Controls means controls (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems) that isolate or remove the bloodborne pathogens hazard from the workplace.

Exposure Incident means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.

Handwashing Facilities means a facility providing an adequate supply of running potable water, soap and single use towels or hot air drying machines.

Licensed Healthcare Professional is a person whose legally permitted scope of practice allows him or her to independently perform the activities required by paragraph (f) Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up.

HBV means hepatitis B virus.

HIV means human immunodeficiency virus.

Needleless systems means a device that does not use needles for:

(1) The collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established; (2) The administration of medication or fluids; or (3) Any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

Occupational Exposure means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.

Other Potentially Infectious Materials means (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

Parenteral means piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, and abrasions.

Personal Protective Equipment is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or

blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.

Production Facility means a facility engaged in industrial-scale, large-volume or high concentration production of HIV or HBV.

Regulated Waste means liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

Research Laboratory means a laboratory producing or using research-laboratory-scale amounts of HIV or HBV. Research laboratories may produce high concentrations of HIV or HBV but not in the volume found in production facilities.

Sharps with engineered sharps injury protections means a nonneedle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.

Source Individual means any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components.

Sterilize means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

Universal Precautions is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.

Work Practice Controls means controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).

1910.1030(c)

Exposure Control --

1910.1030(c)(1)

Exposure Control Plan.

1910.1030(c)(1)(i)

Each employer having an employee(s) with occupational exposure as defined by paragraph (b) of this section shall establish a written Exposure Control Plan designed to eliminate or minimize employee exposure.

1910.1030(c)(1)(ii)

The Exposure Control Plan shall contain at least the following elements:

1910.1030(c)(1)(ii)(A)

The exposure determination required by paragraph (c)(2),

1910.1030(c)(1)(ii)(B)

The schedule and method of implementation for paragraphs (d) Methods of Compliance, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, (g) Communication of Hazards to Employees, and (h) Recordkeeping, of this standard, and

1910.1030(c)(1)(ii)(C)

The procedure for the evaluation of circumstances surrounding exposure incidents as required by paragraph (f)(3)(i) of this standard.

1910.1030(c)(1)(iii)

Each employer shall ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with 29 CFR 1910.1020(e).

1910.1030(c)(1)(iv)

The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure. The review and update of such plans shall also:

1910.1030(c)(1)(iv)(A)

Reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens; and

1910.1030(c)(1)(iv)(B)

Document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure.

1910.1030(c)(1)(v)

An employer, who is required to establish an Exposure Control Plan shall solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan.

1910.1030(c)(1)(vi)

The Exposure Control Plan shall be made available to the Assistant Secretary and the Director upon request for examination and copying.

1910.1030(c)(2)

Exposure Determination.

1910.1030(c)(2)(i)

Each employer who has an employee(s) with occupational exposure as defined by paragraph (b) of this section shall prepare an exposure determination. This exposure determination shall contain the following:

1910.1030(c)(2)(i)(A)

A list of all job classifications in which all employees in those job classifications have occupational exposure;

1910.1030(c)(2)(i)(B)

A list of job classifications in which some employees have occupational exposure, and

1910.1030(c)(2)(i)(C)

A list of all tasks and procedures or groups of closely related task and procedures in which occupational exposure occurs and that are performed by employees in job classifications listed in accordance with the provisions of paragraph (c)(2)(i)(B) of this standard.

1910.1030(c)(2)(ii)

This exposure determination shall be made without regard to the use of personal protective equipment.

1910.1030(d)

Methods of Compliance --

1910.1030(d)(1)

General. Universal precautions shall be observed to prevent contact with blood or other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials.

1910.1030(d)(2)

Engineering and Work Practice Controls.

1910.1030(d)(2)(i)

Engineering and work practice controls shall be used to eliminate or minimize employee exposure. Where occupational exposure remains after institution of these controls, personal protective equipment shall also be used.

1910.1030(d)(2)(ii)

Engineering controls shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness.

1910.1030(d)(2)(iii)

Employers shall provide handwashing facilities which are readily accessible to employees.
1910.1030(d)(2)(iv)
When provision of handwashing facilities is not feasible, the employer shall provide either an appropriate antiseptic hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes. When antiseptic hand cleansers or towelettes are used, hands shall be washed with soap and running water as soon as feasible.
1910.1030(d)(2)(v)
Employers shall ensure that employees wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment.
1910.1030(d)(2)(vi)
Employers shall ensure that employees wash hands and any other skin with soap and water, or flush mucous membranes with water immediately or as soon as feasible following contact of such body areas with blood or other potentially infectious materials.
1910.1030(d)(2)(vii)
Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed except as noted in paragraphs (d)(2)(vii)(A) and (d)(2)(vii)(B) below. Shearing or breaking of contaminated needles is prohibited.
1910.1030(d)(2)(vii)(A)
Contaminated needles and other contaminated sharps shall not be bent, recapped or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure.
1910.1030(d)(2)(vii)(B)
Such bending, recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique.
1910.1030(d)(2)(viii)
Immediately or as soon as possible after use, contaminated reusable sharps shall be placed in appropriate containers until properly reprocessed. These containers shall be:
1910.1030(d)(2)(viii)(A)
Puncture resistant;
1910.1030(d)(2)(viii)(B)
Labeled or color-coded in accordance with this standard;
1910.1030(d)(2)(viii)(C)
Leakproof on the sides and bottom; and
1910.1030(d)(2)(viii)(D)
In accordance with the requirements set forth in paragraph (d)(4)(ii)(E) for reusable sharps.
1910.1030(d)(2)(ix)
Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure.
1910.1030(d)(2)(x)
Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on countertops or benchtops where blood or other potentially infectious materials are present.
1910.1030(d)(2)(xi)
All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances.
1910.1030(d)(2)(xii)
Mouth pipetting/suctioning of blood or other potentially infectious materials is prohibited.
1910.1030(d)(2)(xiii)
Specimens of blood or other potentially infectious materials shall be placed in a container which prevents leakage during collection, handling, processing, storage, transport, or shipping.
1910.1030(d)(2)(xiii)(A)
The container for storage, transport, or shipping shall be labeled or color-coded according to paragraph (g)(1)(i) and closed prior to being stored, transported, or shipped. When a facility utilizes Universal Precautions in the handling of all specimens, the labeling/color-coding of specimens is not necessary provided containers are recognizable as containing specimens. This exemption only applies while such specimens/containers remain within the facility. Labeling or color-coding in accordance with paragraph (g)(1)(i) is required when such specimens/containers leave the facility.
1910.1030(d)(2)(xiii)(B)

If outside contamination of the primary container occurs, the primary container shall be placed within a second container which prevents leakage during handling, processing, storage, transport, or shipping and is labeled or color-coded according to the requirements of this standard.

1910.1030(d)(2)(xiii)(C)

If the specimen could puncture the primary container, the primary container shall be placed within a secondary container which is puncture-resistant in addition to the above characteristics.

1910.1030(d)(2)(xiv)

Equipment which may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary, unless the employer can demonstrate that decontamination of such equipment or portions of such equipment is not feasible.

1910.1030(d)(2)(xiv)(A)

A readily observable label in accordance with paragraph (g)(1)(i)(H) shall be attached to the equipment stating which portions remain contaminated.

1910.1030(d)(2)(xiv)(B)

The employer shall ensure that this information is conveyed to all affected employees, the servicing representative, and/or the manufacturer, as appropriate, prior to handling, servicing, or shipping so that appropriate precautions will be taken.

1910.1030(d)(3)

Personal Protective Equipment --

1910.1030(d)(3)(i)

Provision. When there is occupational exposure, the employer shall provide, at no cost to the employee, appropriate personal protective equipment such as, but not limited to, gloves, gowns, laboratory coats, face shields or masks and eye protection, and mouthpieces, resuscitation bags, pocket masks, or other ventilation devices. Personal protective equipment will be considered "appropriate" only if it does not permit blood or other potentially infectious materials to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used.

1910.1030(d)(3)(ii)

Use. The employer shall ensure that the employee uses appropriate personal protective equipment unless the employer shows that the employee temporarily and briefly declined to use personal protective equipment when, under rare and extraordinary circumstances, it was the employee's professional judgment that in the specific instance its use would have prevented the delivery of health care or public safety services or would have posed an increased hazard to the safety of the worker or co-worker. When the employee makes this judgement, the circumstances shall be investigated and documented in order to determine whether changes can be instituted to prevent such occurrences in the future.

1910.1030(d)(3)(iii)

Accessibility. The employer shall ensure that appropriate personal protective equipment in the appropriate sizes is readily accessible at the worksite or is issued to employees. Hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives shall be readily accessible to those employees who are allergic to the gloves normally provided.

1910.1030(d)(3)(iv)

Cleaning, Laundering, and Disposal. The employer shall clean, launder, and dispose of personal protective equipment required by paragraphs (d) and (e) of this standard, at no cost to the employee.

1910.1030(d)(3)(v)

Repair and Replacement. The employer shall repair or replace personal protective equipment as needed to maintain its effectiveness, at no cost to the employee.

1910.1030(d)(3)(vi)

If a garment(s) is penetrated by blood or other potentially infectious materials, the garment(s) shall be removed immediately or as soon as feasible.

1910.1030(d)(3)(vii)

All personal protective equipment shall be removed prior to leaving the work area.

1910.1030(d)(3)(viii)

When personal protective equipment is removed it shall be placed in an appropriately

designated area or container for storage, washing, decontamination or disposal.
1910.1030(d)(3)(ix)
Gloves. Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, mucous membranes, and non-intact skin; when performing vascular access procedures except as specified in paragraph (d)(3)(ix)(D); and when handling or touching contaminated items or surfaces.
1910.1030(d)(3)(ix)(A)
Disposable (single use) gloves such as surgical or examination gloves, shall be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised.
1910.1030(d)(3)(ix)(B)
Disposable (single use) gloves shall not be washed or decontaminated for re-use.
1910.1030(d)(3)(ix)(C)
Utility gloves may be decontaminated for re-use if the integrity of the glove is not compromised. However, they must be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration or when their ability to function as a barrier is compromised.
1910.1030(d)(3)(ix)(D)
If an employer in a volunteer blood donation center judges that routine gloving for all phlebotomies is not necessary then the employer shall:
1910.1030(d)(3)(ix)(D)(1)
Periodically reevaluate this policy;
1910.1030(d)(3)(ix)(D)(2)
Make gloves available to all employees who wish to use them for phlebotomy;
1910.1030(d)(3)(ix)(D)(3)
Not discourage the use of gloves for phlebotomy; and
1910.1030(d)(3)(ix)(D)(4)
Require that gloves be used for phlebotomy in the following circumstances:
1910.1030(d)(3)(ix)(D)(4)(i)
When the employee has cuts, scratches, or other breaks in his or her skin;
1910.1030(d)(3)(ix)(D)(4)(ii)
When the employee judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative source individual; and
1910.1030(d)(3)(ix)(D)(4)(iii)
When the employee is receiving training in phlebotomy.
1910.1030(d)(3)(x)
Masks, Eye Protection, and Face Shields. Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.
1910.1030(d)(3)(xi)
Gowns, Aprons, and Other Protective Body Clothing. Appropriate protective clothing such as, but not limited to, gowns, aprons, lab coats, clinic jackets, or similar outer garments shall be worn in occupational exposure situations. The type and characteristics will depend upon the task and degree of exposure anticipated.
1910.1030(d)(3)(xii)
Surgical caps or hoods and/or shoe covers or boots shall be worn in instances when gross contamination can reasonably be anticipated (e.g., autopsies, orthopaedic surgery).
1910.1030(d)(4)
Housekeeping --
1910.1030(d)(4)(i)
General. Employers shall ensure that the worksite is maintained in a clean and sanitary condition. The employer shall determine and implement an appropriate written schedule for cleaning and method of decontamination based upon the location within the facility, type of surface to be cleaned, type of soil present, and tasks or procedures being performed in the area.
1910.1030(d)(4)(ii)
All equipment and environmental and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials.
1910.1030(d)(4)(ii)(A)

Contaminated work surfaces shall be decontaminated with an appropriate disinfectant after completion of procedures; immediately or as soon as feasible when surfaces are overtly contaminated or after any spill of blood or other potentially infectious materials; and at the end of the work shift if the surface may have become contaminated since the last cleaning.
1910.1030(d)(4)(ii)(B)
Protective coverings, such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper used to cover equipment and environmental surfaces, shall be removed and replaced as soon as feasible when they become overtly contaminated or at the end of the workshift if they may have become contaminated during the shift.
1910.1030(d)(4)(ii)(C)
All bins, pails, cans, and similar receptacles intended for reuse which have a reasonable likelihood for becoming contaminated with blood or other potentially infectious materials shall be inspected and decontaminated on a regularly scheduled basis and cleaned and decontaminated immediately or as soon as feasible upon visible contamination.
1910.1030(d)(4)(ii)(D)
Broken glassware which may be contaminated shall not be picked up directly with the hands. It shall be cleaned up using mechanical means, such as a brush and dust pan, tongs, or forceps.
1910.1030(d)(4)(ii)(E)
Reusable sharps that are contaminated with blood or other potentially infectious materials shall not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed.
1910.1030(d)(4)(iii)
Regulated Waste --
1910.1030(d)(4)(iii)(A)
Contaminated Sharps Discarding and Containment.
1910.1030(d)(4)(iii)(A)(1)
Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are:
1910.1030(d)(4)(iii)(A)(1)(i)
Closable;
1910.1030(d)(4)(iii)(A)(1)(ii)
Puncture resistant;
1910.1030(d)(4)(iii)(A)(1)(iii)
Leakproof on sides and bottom; and
1910.1030(d)(4)(iii)(A)(1)(iv)
Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard.
1910.1030(d)(4)(iii)(A)(2)
During use, containers for contaminated sharps shall be:
1910.1030(d)(4)(iii)(A)(2)(i)
Easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries);
1910.1030(d)(4)(iii)(A)(2)(ii)
Maintained upright throughout use; and
1910.1030(d)(4)(iii)(A)(2)(iii)
Replaced routinely and not be allowed to overfill.
1910.1030(d)(4)(iii)(A)(3)
When moving containers of contaminated sharps from the area of use, the containers shall be:
1910.1030(d)(4)(iii)(A)(3)(i)
Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping;
1910.1030(d)(4)(iii)(A)(3)(ii)
Placed in a secondary container if leakage is possible. The second container shall be:
1910.1030(d)(4)(iii)(A)(3)(ii)(A)
Closable;
1910.1030(d)(4)(iii)(A)(3)(ii)(B)
Constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping; and
1910.1030(d)(4)(iii)(A)(3)(ii)(C)
Labeled or color-coded according to paragraph (g)(1)(i) of this standard.

1910.1030(d)(4)(iii)(A)(4)
Reusable containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury.
1910.1030(d)(4)(iii)(B)
Other Regulated Waste Containment --
1910.1030(d)(4)(iii)(B)(1)
Regulated waste shall be placed in containers which are:
1910.1030(d)(4)(iii)(B)(1)(i)
Closable;
1910.1030(d)(4)(iii)(B)(1)(ii)
Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;
1910.1030(d)(4)(iii)(B)(1)(iii)
Labeled or color-coded in accordance with paragraph (g)(1)(i) this standard; and
1910.1030(d)(4)(iii)(B)(1)(iv)
Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.
1910.1030(d)(4)(iii)(B)(2)
If outside contamination of the regulated waste container occurs, it shall be placed in a second container. The second container shall be:
1910.1030(d)(4)(iii)(B)(2)(i)
Closable;
1910.1030(d)(4)(iii)(B)(2)(ii)
Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;
1910.1030(d)(4)(iii)(B)(2)(iii)
Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard; and
1910.1030(d)(4)(iii)(B)(2)(iv)
Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.
1910.1030(d)(4)(iii)(C)
Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories.
1910.1030(d)(4)(iv)
Laundry.
1910.1030(d)(4)(iv)(A)
Contaminated laundry shall be handled as little as possible with a minimum of agitation.
1910.1030(d)(4)(iv)(A)(1)
Contaminated laundry shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use.
1910.1030(d)(4)(iv)(A)(2)
Contaminated laundry shall be placed and transported in bags or containers labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard. When a facility utilizes Universal Precautions in the handling of all soiled laundry, alternative labeling or color-coding is sufficient if it permits all employees to recognize the containers as requiring compliance with Universal Precautions.
1910.1030(d)(4)(iv)(A)(3)
Whenever contaminated laundry is wet and presents a reasonable likelihood of soak-through of or leakage from the bag or container, the laundry shall be placed and transported in bags or containers which prevent soak-through and/or leakage of fluids to the exterior.
1910.1030(d)(4)(iv)(B)
The employer shall ensure that employees who have contact with contaminated laundry wear protective gloves and other appropriate personal protective equipment.
1910.1030(d)(4)(iv)(C)
When a facility ships contaminated laundry off-site to a second facility which does not utilize Universal Precautions in the handling of all laundry, the facility generating the contaminated laundry must place such laundry in bags or containers which are labeled or color-coded in accordance with paragraph (g)(1)(i).
1910.1030(e)
HIV and HBV Research Laboratories and Production Facilities.
1910.1030(e)(1)

This paragraph applies to research laboratories and production facilities engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV. It does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs. These requirements apply in addition to the other requirements of the standard.

1910.1030(e)(2)

Research laboratories and production facilities shall meet the following criteria:

1910.1030(e)(2)(i)

Standard Microbiological Practices. All regulated waste shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

1910.1030(e)(2)(ii)

Special Practices.

1910.1030(e)(2)(ii)(A)

Laboratory doors shall be kept closed when work involving HIV or HBV is in progress.

1910.1030(e)(2)(ii)(B)

Contaminated materials that are to be decontaminated at a site away from the work area shall be placed in a durable, leakproof, labeled or color-coded container that is closed before being removed from the work area.

1910.1030(e)(2)(ii)(C)

Access to the work area shall be limited to authorized persons. Written policies and procedures shall be established whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements, and who comply with all entry and exit procedures shall be allowed to enter the work areas and animal rooms.

1910.1030(e)(2)(ii)(D)

When other potentially infectious materials or infected animals are present in the work area or containment module, a hazard warning sign incorporating the universal biohazard symbol shall be posted on all access doors. The hazard warning sign shall comply with paragraph (g)(1)(ii) of this standard.

1910.1030(e)(2)(ii)(E)

All activities involving other potentially infectious materials shall be conducted in biological safety cabinets or other physical-containment devices within the containment module. No work with these other potentially infectious materials shall be conducted on the open bench.

1910.1030(e)(2)(ii)(F)

Laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing shall be used in the work area and animal rooms. Protective clothing shall not be worn outside of the work area and shall be decontaminated before being laundered.

1910.1030(e)(2)(ii)(G)

Special care shall be taken to avoid skin contact with other potentially infectious materials. Gloves shall be worn when handling infected animals and when making hand contact with other potentially infectious materials is unavoidable.

1910.1030(e)(2)(ii)(H)

Before disposal all waste from work areas and from animal rooms shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

1910.1030(e)(2)(ii)(I)

Vacuum lines shall be protected with liquid disinfectant traps and high-efficiency particulate air (HEPA) filters or filters of equivalent or superior efficiency and which are checked routinely and maintained or replaced as necessary.

1910.1030(e)(2)(ii)(J)

Hypodermic needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., the needle is integral to the syringe) shall be used for the injection or aspiration of other potentially infectious materials. Extreme caution shall be used when handling needles and syringes. A needle shall not be bent, sheared, replaced in the sheath or guard, or removed from the syringe following use. The needle and syringe shall be promptly placed in a puncture-resistant container and autoclaved or decontaminated before reuse or disposal.

1910.1030(e)(2)(ii)(K)

All spills shall be immediately contained and cleaned up by appropriate professional staff or others properly trained and equipped to work with potentially concentrated infectious materials.

1910.1030(e)(2)(ii)(L)

A spill or accident that results in an exposure incident shall be immediately reported to the laboratory director or other responsible person.

1910.1030(e)(2)(ii)(M)

A biosafety manual shall be prepared or adopted and periodically reviewed and updated at least annually or more often if necessary. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.

1910.1030(e)(2)(iii)

Containment Equipment.

1910.1030(e)(2)(iii)(A)

Certified biological safety cabinets (Class I, II, or III) or other appropriate combinations of personal protection or physical containment devices, such as special protective clothing, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals, shall be used for all activities with other potentially infectious materials that pose a threat of exposure to droplets, splashes, spills, or aerosols.

1910.1030(e)(2)(iii)(B)

Biological safety cabinets shall be certified when installed, whenever they are moved and at least annually.

1910.1030(e)(3)

HIV and HBV research laboratories shall meet the following criteria:

1910.1030(e)(3)(i)

Each laboratory shall contain a facility for hand washing and an eye wash facility which is readily available within the work area.

1910.1030(e)(3)(ii)

An autoclave for decontamination of regulated waste shall be available.

1910.1030(e)(4)

HIV and HBV production facilities shall meet the following criteria:

1910.1030(e)(4)(i)

The work areas shall be separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of doors shall be the basic requirement for entry into the work area from access corridors or other contiguous areas. Physical separation of the high-containment work area from access corridors or other areas or activities may also be provided by a double-doored clothes-change room (showers may be included), airlock, or other access facility that requires passing through two sets of doors before entering the work area.

1910.1030(e)(4)(ii)

The surfaces of doors, walls, floors and ceilings in the work area shall be water resistant so that they can be easily cleaned. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontamination.

1910.1030(e)(4)(iii)

Each work area shall contain a sink for washing hands and a readily available eye wash facility. The sink shall be foot, elbow, or automatically operated and shall be located near the exit door of the work area.

1910.1030(e)(4)(iv)

Access doors to the work area or containment module shall be self-closing.

1910.1030(e)(4)(v)

An autoclave for decontamination of regulated waste shall be available within or as near as possible to the work area.

1910.1030(e)(4)(vi)

A ducted exhaust-air ventilation system shall be provided. This system shall create directional airflow that draws air into the work area through the entry area. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes. The proper direction of the airflow shall be verified (i.e., into the work area).

1910.1030(e)(5)

Training Requirements. Additional training requirements for employees in HIV and HBV

research laboratories and HIV and HBV production facilities are specified in paragraph (g)(2)(ix).

1910.1030(f)

Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up --

1910.1030(f)(1)

General.

1910.1030(f)(1)(i)

The employer shall make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure, and post-exposure evaluation and follow-up to all employees who have had an exposure incident.

1910.1030(f)(1)(ii)

The employer shall ensure that all medical evaluations and procedures including the hepatitis B vaccine and vaccination series and post-exposure evaluation and follow-up, including prophylaxis, are:

1910.1030(f)(1)(ii)(A)

Made available at no cost to the employee;

1910.1030(f)(1)(ii)(B)

Made available to the employee at a reasonable time and place;

1910.1030(f)(1)(ii)(C)

Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional; and

1910.1030(f)(1)(ii)(D)

Provided according to recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place, except as specified by this paragraph (f).

1910.1030(f)(1)(iii)

The employer shall ensure that all laboratory tests are conducted by an accredited laboratory at no cost to the employee.

1910.1030(f)(2)

Hepatitis B Vaccination.

1910.1030(f)(2)(i)

Hepatitis B vaccination shall be made available after the employee has received the training required in paragraph (g)(2)(vii)(I) and within 10 working days of initial assignment to all employees who have occupational exposure unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons.

1910.1030(f)(2)(ii)

The employer shall not make participation in a prescreening program a prerequisite for receiving hepatitis B vaccination.

1910.1030(f)(2)(iii)

If the employee initially declines hepatitis B vaccination but at a later date while still covered under the standard decides to accept the vaccination, the employer shall make available hepatitis B vaccination at that time.

1910.1030(f)(2)(iv)

The employer shall assure that employees who decline to accept hepatitis B vaccination offered by the employer sign the statement in Appendix A.

1910.1030(f)(2)(v)

If a routine booster dose(s) of hepatitis B vaccine is recommended by the U.S. Public Health Service at a future date, such booster dose(s) shall be made available in accordance with section (f)(1)(ii).

1910.1030(f)(3)

Post-exposure Evaluation and Follow-up. Following a report of an exposure incident, the employer shall make immediately available to the exposed employee a confidential medical evaluation and follow-up, including at least the following elements:

1910.1030(f)(3)(i)

Documentation of the route(s) of exposure, and the circumstances under which the exposure incident occurred;

1910.1030(f)(3)(ii)

Identification and documentation of the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law;

1910.1030(f)(3)(ii)(A)

The source individual's blood shall be tested as soon as feasible and after consent is obtained

in order to determine HBV and HIV infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented.

1910.1030(f)(3)(ii)(B)

When the source individual is already known to be infected with HBV or HIV, testing for the source individual's known HBV or HIV status need not be repeated.

1910.1030(f)(3)(ii)(C)

Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.

1910.1030(f)(3)(iii)

Collection and testing of blood for HBV and HIV serological status;

1910.1030(f)(3)(iii)(A)

The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained.

1910.1030(f)(3)(iii)(B)

If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible.

1910.1030(f)(3)(iv)

Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service;

1910.1030(f)(3)(v)

Counseling; and

1910.1030(f)(3)(vi)

Evaluation of reported illnesses.

1910.1030(f)(4)

Information Provided to the Healthcare Professional.

1910.1030(f)(4)(i)

The employer shall ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination is provided a copy of this regulation.

1910.1030(f)(4)(ii)

The employer shall ensure that the healthcare professional evaluating an employee after an exposure incident is provided the following information:

1910.1030(f)(4)(ii)(A)

A copy of this regulation;

1910.1030(f)(4)(ii)(B)

A description of the exposed employee's duties as they relate to the exposure incident;

1910.1030(f)(4)(ii)(C)

Documentation of the route(s) of exposure and circumstances under which exposure occurred;

1910.1030(f)(4)(ii)(D)

Results of the source individual's blood testing, if available; and

1910.1030(f)(4)(ii)(E)

All medical records relevant to the appropriate treatment of the employee including vaccination status which are the employer's responsibility to maintain.

1910.1030(f)(5)

Healthcare Professional's Written Opinion. The employer shall obtain and provide the employee with a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation.

1910.1030(f)(5)(i)

The healthcare professional's written opinion for Hepatitis B vaccination shall be limited to whether Hepatitis B vaccination is indicated for an employee, and if the employee has received such vaccination.

1910.1030(f)(5)(ii)

The healthcare professional's written opinion for post-exposure evaluation and follow-up shall be limited to the following information:

1910.1030(f)(5)(ii)(A)

That the employee has been informed of the results of the evaluation; and

1910.1030(f)(5)(ii)(B)
That the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment.
1910.1030(f)(5)(iii)
All other findings or diagnoses shall remain confidential and shall not be included in the written report.
1910.1030(f)(6)
Medical Recordkeeping. Medical records required by this standard shall be maintained in accordance with paragraph (h)(1) of this section.
1910.1030(g)
Communication of Hazards to Employees --
1910.1030(g)(1)
Labels and Signs --
1910.1030(g)(1)(i)
Labels.
1910.1030(g)(1)(i)(A)
Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material; and other containers used to store, transport or ship blood or other potentially infectious materials, except as provided in paragraph (g)(1)(i)(E), (F) and (G).
1910.1030(g)(1)(i)(B)
Labels required by this section shall include the following legend:

1910.1030(g)(1)(i)(C)
These labels shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color.
1910.1030(g)(1)(i)(D)
Labels shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.
1910.1030(g)(1)(i)(E)
Red bags or red containers may be substituted for labels.
1910.1030(g)(1)(i)(F)
Containers of blood, blood components, or blood products that are labeled as to their contents and have been released for transfusion or other clinical use are exempted from the labeling requirements of paragraph (g).
1910.1030(g)(1)(i)(G)
Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal are exempted from the labeling requirement.
1910.1030(g)(1)(i)(H)
Labels required for contaminated equipment shall be in accordance with this paragraph and shall also state which portions of the equipment remain contaminated.
1910.1030(g)(1)(i)(I)
Regulated waste that has been decontaminated need not be labeled or color-coded.
1910.1030(g)(1)(ii)
Signs.
1910.1030(g)(1)(ii)(A)
The employer shall post signs at the entrance to work areas specified in paragraph (e), HIV

and HBV Research Laboratory and Production Facilities, which shall bear the following legend:

(Name of the Infectious Agent)
(Special requirements for entering the area)
(Name, telephone number of the laboratory director or other responsible person.)

1910.1030(g)(1)(ii)(B)

These signs shall be fluorescent orange-red or predominantly so, with lettering and symbols in a contrasting color.

1910.1030(g)(2)

Information and Training.

1910.1030(g)(2)(i)

The employer shall train each employee with occupational exposure in accordance with the requirements of this section. Such training must be provided at no cost to the employee and during working hours. The employer shall institute a training program and ensure employee participation in the program.

1910.1030(g)(2)(ii)

Training shall be provided as follows:

1910.1030(g)(2)(ii)(A)

At the time of initial assignment to tasks where occupational exposure may take place;

1910.1030(g)(2)(ii)(B)

At least annually thereafter.

1910.1030(g)(2)(iii)

[Reserved]

1910.1030(g)(2)(iv)

Annual training for all employees shall be provided within one year of their previous training.

1910.1030(g)(2)(v)

Employers shall provide additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee's occupational exposure. The additional training may be limited to addressing the new exposures created.

1910.1030(g)(2)(vi)

Material appropriate in content and vocabulary to educational level, literacy, and language of employees shall be used.

1910.1030(g)(2)(vii)

The training program shall contain at a minimum the following elements:

1910.1030(g)(2)(vii)(A)

An accessible copy of the regulatory text of this standard and an explanation of its contents;

1910.1030(g)(2)(vii)(B)

A general explanation of the epidemiology and symptoms of bloodborne diseases;

1910.1030(g)(2)(vii)(C)

An explanation of the modes of transmission of bloodborne pathogens;

1910.1030(g)(2)(vii)(D)

An explanation of the employer's exposure control plan and the means by which the employee can obtain a copy of the written plan;

1910.1030(g)(2)(vii)(E)

An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials;

1910.1030(g)(2)(vii)(F)
An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protective equipment;
1910.1030(g)(2)(vii)(G)
Information on the types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment;
1910.1030(g)(2)(vii)(H)
An explanation of the basis for selection of personal protective equipment;
1910.1030(g)(2)(vii)(I)
Information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge;
1910.1030(g)(2)(vii)(J)
Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials;
1910.1030(g)(2)(vii)(K)
An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available;
1910.1030(g)(2)(vii)(L)
Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident;
1910.1030(g)(2)(vii)(M)
An explanation of the signs and labels and/or color coding required by paragraph (g)(1); and
1910.1030(g)(2)(vii)(N)
An opportunity for interactive questions and answers with the person conducting the training session.
1910.1030(g)(2)(viii)
The person conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address.
1910.1030(g)(2)(ix)
Additional Initial Training for Employees in HIV and HBV Laboratories and Production Facilities. Employees in HIV or HBV research laboratories and HIV or HBV production facilities shall receive the following initial training in addition to the above training requirements.
1910.1030(g)(2)(ix)(A)
The employer shall assure that employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV or HBV.
1910.1030(g)(2)(ix)(B)
The employer shall assure that employees have prior experience in the handling of human pathogens or tissue cultures before working with HIV or HBV.
1910.1030(g)(2)(ix)(C)
The employer shall provide a training program to employees who have no prior experience in handling human pathogens. Initial work activities shall not include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed. The employer shall assure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.
1910.1030(h)
Recordkeeping --
1910.1030(h)(1)
Medical Records.
1910.1030(h)(1)(i)
The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.1020.
1910.1030(h)(1)(ii)
This record shall include:
1910.1030(h)(1)(ii)(A)
The name and social security number of the employee;
1910.1030(h)(1)(ii)(B)
A copy of the employee's hepatitis B vaccination status including the dates of all the hepatitis

B vaccinations and any medical records relative to the employee's ability to receive vaccination as required by paragraph (f)(2);
1910.1030(h)(1)(ii)(C)
A copy of all results of examinations, medical testing, and follow-up procedures as required by paragraph (f)(3);
1910.1030(h)(1)(ii)(D)
The employer's copy of the healthcare professional's written opinion as required by paragraph (f)(5); and
1910.1030(h)(1)(ii)(E)
A copy of the information provided to the healthcare professional as required by paragraphs (f)(4)(ii)(B)(C) and (D).
1910.1030(h)(1)(iii)
Confidentiality. The employer shall ensure that employee medical records required by paragraph (h)(1) are:
1910.1030(h)(1)(iii)(A)
Kept confidential; and
1910.1030(h)(1)(iii)(B)
Not disclosed or reported without the employee's express written consent to any person within or outside the workplace except as required by this section or as may be required by law.
1910.1030(h)(1)(iv)
The employer shall maintain the records required by paragraph (h) for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.1020.
1910.1030(h)(2)
Training Records.
1910.1030(h)(2)(i)
Training records shall include the following information:
1910.1030(h)(2)(i)(A)
The dates of the training sessions;
1910.1030(h)(2)(i)(B)
The contents or a summary of the training sessions;
1910.1030(h)(2)(i)(C)
The names and qualifications of persons conducting the training; and
1910.1030(h)(2)(i)(D)
The names and job titles of all persons attending the training sessions.
1910.1030(h)(2)(ii)
Training records shall be maintained for 3 years from the date on which the training occurred.
1910.1030(h)(3)
Availability.
1910.1030(h)(3)(i)
The employer shall ensure that all records required to be maintained by this section shall be made available upon request to the Assistant Secretary and the Director for examination and copying.
1910.1030(h)(3)(ii)
Employee training records required by this paragraph shall be provided upon request for examination and copying to employees, to employee representatives, to the Director, and to the Assistant Secretary.
1910.1030(h)(3)(iii)
Employee medical records required by this paragraph shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.1020.
1910.1030(h)(4)
Transfer of Records.
1910.1030(h)(4)(i)
The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.1020(h).
1910.1030(h)(4)(ii)
If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify the Director, at least

three months prior to their disposal and transmit them to the Director, if required by the Director to do so, within that three month period.

1910.1030(h)(5)

Sharps injury log.

1910.1030(h)(5)(i)

The employer shall establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log shall contain, at a minimum:

1910.1030(h)(5)(i)(A)

The type and brand of device involved in the incident,

1910.1030(h)(5)(i)(B)

The department or work area where the exposure incident occurred, and

1910.1030(h)(5)(i)(C)

An explanation of how the incident occurred.

1910.1030(h)(5)(ii)

The requirement to establish and maintain a sharps injury log shall apply to any employer who is required to maintain a log of occupational injuries and illnesses under 29 CFR 1904.

1910.1030(h)(5)(iii)

The sharps injury log shall be maintained for the period required by 29 CFR 1904.6.

1910.1030(i)

Dates --

1910.1030(i)(1)

Effective Date. The standard shall become effective on March 6, 1992.

1910.1030(i)(2)

The Exposure Control Plan required by paragraph (c) of this section shall be completed on or before May 5, 1992.

1910.1030(i)(3)

Paragraph (g)(2) Information and Training and (h) Recordkeeping shall take effect on or before June 4, 1992.

1910.1030(i)(4)

Paragraphs (d)(2) Engineering and Work Practice Controls, (d)(3) Personal Protective Equipment, (d)(4) Housekeeping, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, and (g)(1) Labels and Signs, shall take effect July 6, 1992.

[56 FR 64004, Dec. 06, 1991, as amended at 57 FR 12717, April 13, 1992; 57 FR 29206, July 1, 1992; 61 FR 5507, Feb. 13, 1996; 66 FR 5325 Jan., 18, 2001; 71 FR 16672 and 16673, April 3, 2006; 73 FR 75586, Dec. 12, 2008]

Next Standard (1910.1030 App A)

Regulations (Standards - 29 CFR) - Table of Contents

Back to Top www.osha.gov www

Occupational Safety & Health Administration
200 Constitution Avenue, NW
Washington, DC 20210

SHIPMENT DATE:_________________________	RECEIPT DATE:____________________________
SHIPPED BY:_____________________________	RECEIVED BY:_____________________________

B1=BLOOD MANGANESE **S1=SST TUBE OR 5 ML NALGENE CRYOVIAL**
√=SPECIMEN COLLECTED **X=SPECIMEN NOT COLLECTED**

	B1		**Comments:**		**B1**		**Comments:**
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SOP FOR GENERAL DATA MANAGEMENT

Dr. Rosemarie Bowler
San Francisco State University

An Epidemiologic Health Study of Manganese Exposure in adult residents of East Liverpool, Ohio

Standard Operating Procedure

General Data Management

Update Date: July 29, 2011

Review Date: September 30, 2011

Reviewed and Approved by: Rosemarie Bowler

1.0 Purpose

This standard operating procedure (SOP) describes the data management process which will be used to construct the final data set for statistical analysis.

2.0 Personnel

1) Project investigators and our statistics consultant will provide technical guidance.

2) Staff from Quality Assurance (QA) unit will be conducting testing and validation of the final database.

3) Study coordinator will provide general support to all phases of this procedure.

3.0 Procedure

1) The documentation for recruiting participants and data collection is available in the IRB protocol (see above), including the neurophysiological test battery descriptions and the SOP “Data collection and testing procedures”.

2) All programming code used for collecting, storing, and converting data is documented and stored in the central server used for this study.

4) From the SOP Derivation of East Liverpool Data (to be written), the daily pollutant data set will be assembled, and named EPA.EL.Marietta.dataset containing the variables listed and described in the codebook “EL.Marietta Codebook”:

5) Each of these datasets will have a structure of one set of scores per row. The data format for these datasets will be in EXCEL, SPSS, and SAS for analysis; however, the source of the data will be in SPSS from which the data can be transported to the other formats.

When data corrections are made, they will be made only in SPSS dataset and the data will be converted again to the other formats. The changes can only be made by the data manager of the study after the data have been locked for analysis. Documentation will be kept to indicate date/time and reason for data corrections.

4.0 Testing and Validation by Quality Assurance (QA)

1) QA staff will examine the distributions of variables in dataset EPA.EL.Marietta.dataset and check to ensure that the computed scores for various subscales accurately reflect the totals based on the individual items which make up the scales.

2) QA staff will randomly select 10% of the entered records for data entry errors. These records will be evenly distributed based on which staff entered the data, so that each member of data entry personnel will have their work checked evenly.

2) The results of the QA assessment will be documented and presented to senior personnel.

INCIDENT LOG

INCIDENT LOG

Report all incidents which are not planned under Standard Operating Procedures

Time and Date	**Description of Incident**	**Action Taken**	**Supervisor Signature**

UPDRS: ADL AND MOTOR SCALES

Selected Motor and ADL Items from the UPDRS

ID:_____Date:_____

I. **Activities of Daily Living**

- **1 . Speech**

0-normal
1-mildly affected, no difficulty being understood
2-moderately affected, may be asked to repeat
3-severely affected, frequently asked to repeat
4-unintelligible most of time

- **2 . Salivation**

0-normal
1-slight but noticeable increase, may have nighttime drooling
2-moderately excessive saliva, hay minimal drooling
3-marked drooling

- **3 . Swallowing**

0-normal
1-rare choking
2-occasional choking
3-requires soft food
4-requires NG tube or G-tube

- **4. Handwriting**

0-normal
1-slightly small or slow
2-all words small but legible
3-severely affected, not all words legible
4-majority illegible

- **5. Cutting Food/Handing Utensils**

0-normal
1-somewhat slow and clumsy but no help needed
2-can cut most foods, some help needed
3-food must be cut, but can feed self
4-needs to be fed

- **6. Dressing**

0-normal
1-somewhat slow, no help needed
2-occasional help with buttons or arms in sleeves
3-considerable help required but can do something alone
4-helpless

- **7. Hygiene**

0-normal
1-somewhat slow but no help needed
2-needs help with shower or bath or very slow in hygienic care
3-requires assistance for washing, brushing teeth, going to bathroom
4-helpless

- **8. Turning in Bed/ Adjusting Bed Clothes**

0-normal
1-somewhat slow no help needed
2-can turn alone or adjust sheets but with great difficulty
3-san initiate but not turn or adjust alone
4-helpless

- **9. Falling-Unrelated to Freezing**

0-none
1-rare falls
2-occasional, less than one per day
3-average of once per day
4->1 per day

- **10. Freezing When Walking**

0-normal

1-rare, may have start hesitation
2-occasional falls from freezing,
3-frequent freezing, occasional falls
4-frequent falls from freezin

- **12. Walking**

0-normal
1-mild difficulty, day drag legs or decrease arm swing
2-moderate difficultly requires no assist
3-severe disturbance requires assistance
4-cannot walk at all even with assist

- **13. Tremor**

0-absent
1-slight and infrequent, not bothersome to patient
2-moderate, bothersome to patient
3-severe, interfere with many activities
4-marked, interferes with many activities

- **14. Sensory Complaints Related to Parkinsonism**

0-none
1-occasionally has numbness, tingling, and mild aching
2-frequent, but not distressing
3-frequent painful sensation
4-excruciating pain

II. **Motor Exam**

- **1. Speech**

0-normal
1-slight loss of expression, diction,volume
2-monotone, slurred but understandable, mod. impaired
3-marked impairment, difficult to understand
4-unintelligible

- **2. Facial Expression**

0-Normal

1-slight hypomymia, could be poker face
2-slight but definite abnormal diminution in expression
3-mod. hypomimia, lips parted some of time
4-masked or fixed face, lips parted 1/4 of inch or more with complete loss of expression

- **4. Tremor at Rest**
  - **Face**

0-absent
1-slight and infrequent
2-mild and present most of time
3-moderate and present most of time
4-marked and present most of time

  - **5. Right Upper Extremity (RUE)**

0-absent
1-slight and infrequent
2-mild and present most of time
3-moderate and present most of time
4-marked and present most of time

  - **6. LUE**

0-absent
1-slight and infrequent
2-mild and present most of time
3-moderate and present most of time
4-marked and present most of time

  - **7. RLE**

0-absent
1-slight and infrequent
2-mild and present most of time
3-moderate and present most of time
4-marked and present most of time

  - **8. LLE**

0-absent
1-slight and infrequent
2-mild and present most of time
3-moderate and present most of time
4-marked and present most of time

- **Action or Postural Tremor**
  - **9. RUE**

0-absent
1-slight, present with action
2-moderate, present with action
3-moderate present with action and posture holding
4-marked, interferes with feeding

  - **10. LUE**

0-absent
1-slight, present with action
2-moderate, present with action
3-moderate present with action and posture holding
4-marked, interferes with feeding

- **Rigidity**
  - **11. Neck**

0-absent
1-slight or only with activation
2-mild/moderate
3-marked, full range of motion
4-severe

  - **12. RUE**

0-absent
1-slight or only with activation
2-mild/moderate
3-marked, full range of motion
4-severe

  - **13. LUE**

0-absent
1-slight or only with activation
2-mild/moderate
3-marked, full range of motion
4-severe

- **14. RLE**

0-absent
1-slight or only with activation
2-mild/moderate
3-marked, full range of motion
4-severe

- **15. LLE**

0-absent
1-slight or only with activation
2-mild/moderate
3-marked, full range of motion
4-severe

- **Finger taps**
  - **16. Right**

0-normal
1-mild slowing, and/or reduction in amp.
2-moderate impaired. Definite and early fatiguing, may have occasional arrests
3-severely impaired. Frequent hesitations and arrests.
4-can barely perform

- **17. Left**

0-normal
1-mild slowing, and/or reduction in amp.
2-moderate impaired. Definite and early fatiguing, may have occasional arrests
3-severely impaired. Frequent hesitations and arrests.
4-can barely perform

- **Hand Movements (open and close hands in rapid succession)**
  - **18. Right**

0-normal
1-mild slowing, and/or reduction in amp.
2-moderate impaired. Definite and early fatiguing, may have occasional arrests
3-severely impaired. Frequent hesitations and arrests.
4-can barely perform

- **19. Left**

0-normal
1-mild slowing, and/or reduction in amp.
2-moderate impaired. Definite and early fatiguing, may have occasional arrests
3-severely impaired. Frequent hesitations and arrests.
4-can barely perform

- **Rapid Alternating Movements (pronate and supinate hands)**
  - **20. Right**

0-normal
1-mild slowing, and/or reduction in amp.
2-moderate impaired. Definite and early fatiguing, may have occasional arrests
3-severely impaired. Frequent hesitations and arrests.
4-can barely perform

- **21. Left**

0-normal
1-mild slowing, and/or reduction in amp.
2-moderate impaired. Definite and early fatiguing, may have occasional arrests
3-severely impaired. Frequent hesitations and arrests.
4-can barely perform

- **Leg Agility (tap heel on ground, amp should be 3 inches)**
  - **22. Right**

0-normal
1-mild slowing, and/or reduction in amp.
2-moderate impaired. Definite and early fatiguing, may have occasional arrests
3-severely impaired. Frequent hesitations and arrests.
4-can barely perform

- **23. Left**

0-normal
1-mild slowing, and/or reduction in amp.
2-moderate impaired. Definite and early fatiguing, may have occasional arrests
3-severely impaired. Frequent hesitations and arrests.
4-can barely perform

- **24. Arising From Chair (pt. arises with arms folded across chest)**

0-normal
1-slow, may need more than one attempt
2-pushes self up from arms or seat
3-tends to fall back, may need multiple tries but can arise without assistance
4-unable to arise without help

- **25. Posture**

0-normal erect
1-slightly stooped, could be normal for older person
2-definitely abnormal, mod. stooped, may lean to one side
3-severely stooped with kyphosis
4-marked flexion with extreme abnormality of posture

- **26. Gait**

0-normal
1-walks slowly, may shuffle with short steps, no festination or propulsion
2-walks with difficulty, little or no assistance, some festination, short steps or propulsion
3-severe disturbance, frequent assistance
4-cannot walk

- **27. Postural Stability (retropulsion test)**

0-normal
1-recovers unaided
2-would fall if not caught
3-falls spontaneously
4-unable to stand

- **28. Body Bradykinesia/ Hypokinesia**

0-none
1-minimal slowness, could be normal, deliberate character
2-mild slowness and poverty of movement, definitely abnormal, or dec. amp. of movement
3-moderate slowness, poverty, or small amplitude
4-marked slowness, poverty, or amplitude

TESTING CHECKLIST

East Liverpool Testing Checklist

ID: _____ **DATE:** _____

Check-in TIME: _____

Test Battery & Questionnaires

(initial when completed)

___ Consent form (give copy)

Cognitive — Lg Blue

___ Trails A & B
___ Digit Span
___ Rey-O Copy
___ Animal Naming
___ Rey-O Immediate Recall
___ NAB: Memory Module
___ Rey-O Delayed
___ Similarities
___ Rey 15
___ Digit Symbol Coding
___ Parallel Lines
___ ACT
___ Stroop Color Word Test

VSVT needed?: Y N

___ VSVT complete

Blood — Lg Pink

___ Blood Drawn

Hair and Toenails — Lg White

___ Hair and Toenails collected

(initial when completed)

Questionnaires — Lg Green

___ SCL 90-R
___ BRFSS
___ Satisfaction with Life
___ EWS
___ Health Questionnaire

Motor & Tremor — Lg Purple

___ Grooved Pegboard
___ Fingertapping
___ Dynamometer

Other

___ CATSYS — Sm Green
___ UPDRS — Sm Orange

Medical History — Lg Yellow

___ Reviewed by Dr. Kim

☐ Gift Card Received

☐ File Complete

Check-out TIME: _____

RECRUITMENT LETTER

September 6, 2011

East Liverpool (EL) Community Health Study
Meeting at the EL Motor Lodge on September 15, 6:30pm

Mr. XXXXXX or current resident
Street Address
EAST LIVERPOOL, OH 43925

Dear Mr. XXXXXX or current resident,

My name is Professor Rosemarie Bowler, a faculty member at San Francisco State University in the Psychology Department. You may have seen in the local media that we are conducting research on the potential health effects of exposure to manganese in adults in your community. To examine these health effects, we are recruiting 100 adults in East Liverpool for participation. You have been randomly selected as a possible participant in our study. Any two members of your household between 30-75 years of age are invited to take part in the study.

We invite you to come to the first Health Study community meeting at the EL Motor Lodge, 2340 Dresden Ave., East Liverpool OH, on Thursday Sept. 15, 2011 at 6:30 pm where I will discuss the study and answer your questions. Collaborators from the U.S. Environmental Protection Agency (EPA), Ohio Department of Health (ODH), and the Agency for Toxic Substances and Disease Registry (ATSDR) will also be present.

Each person participating in the study will receive a $50.00 gift card as a token of our appreciation. Additionally, each participant will receive his/her personal results of the health screening. The total time commitment we ask of you may be between 2½ to 4 hours. Testing is taking place at the EL Motor Lodge in East Liverpool on November 3rd, 4th, 5th & 6th mornings and afternoons. Participation in this study will involve:

- asking you about your health and residential history, sleep, diet, and mood status;
- measuring cognitive functioning, including memory, attention, learning, and visual/spatial skills;
- testing dexterity and strength;
- reviewing your medical history with a doctor who specializes in neurology; and
- collecting a few biological samples to see what amounts of metals are being stored in your blood, hair, and toe nails.

Please note that all of your health information will be kept confidential.

If you are interested in participating in the study, please complete the enclosed self-addressed stamped postcard with your name, phone number, and email (if you have one), and mail it to us at your earliest convenience. Once we receive this card from you we will contact you by phone and a representative of our study team will ask you a few questions to determine if your background meets the study participation criteria. We will also answer any questions you might have about the study. Thank you for considering participating in the East Liverpool Community Health Study!

Sincerely,

Rosemarie R. Bowler, Ph.D.

Rosemarie Bowler, Ph.D.

CHAIN OF CUSTODY FOR BLOOD SAMPLES

KONELAB
Analysis Request/Chain Of Custody Form

Request forms should be received by Judy Richards (B581 or B580-A, Ext. 1-2398 or 1-0507) **10-14** days prior to submission of experimental samples. Following the above submission times ensures there will be adequate time for review of your request(s) so that proper samples and/or sample preparations (i.e. plasma *vs.* serum, buffer composition, storage: 4^0C, -20^0C, -80^0C) are performed to ensure quality data results. Because of the demand for this service, samples will be assayed in chronological order according to dated scheduling sheets unless special circumstances dictate otherwise and pre-approved by Ian Gilmour. If same day analysis is required (i.e. urine samples, etc.), please check with Judy ***at least (2 to 3 weeks in advance)*** to avoid scheduling conflicts. Numbers on samples should be labeled in unique consecutive numerical order (i.e. 1, 2, 3…N).

Name:

Branch/Div.:

Phone:

Type of sample(s):

Date when samples will be transferred:

Number of samples per date:

Label numbers per date:

Konelab assays:

Investigator signature:_____
Date:_____
Investigator Comments:

Acceptable: YES ( ) NO ( ) Signed by:_____
Date:_____
Comments:

EMERGENCY CONTACTS

LIST OF EMERGENCY CONTACTS

East Liverpool

Primary Emergency Number 911

East Liverpool Hospital	(330) 385-7200
Police Department	(330) 385-1234
Fire Department	(330) 385-1117

Office Emergency Contact Information

Dr. Bowler

Cell Phone: 510-290-1065
email: rbowl@sfsu.edu
Emergency Contact: Stephen Rauch
(510) 526-2120

Beth Stutzman

Cell Phone: (971) 218-3035
Email: bethnstutzman@gmail.com
Emergency Contact: Sharon or Jerry Stutzman
(503) 391-4771

Katherine Brown

Cell Phone: 707-980-2062
email: kbrown@alliant.edu
Emergency Contact: Lisa Sheridan
(415) 710-0021

Matthew Harris

Cell Phone: 831-334-1007
email: MHarris2@alliant.edu
Emergency Contact: Debra Harris
(831) 462-1007

Jessica Warren

Cell Phone: 818-521-9321
email: jessicamercedeswarren@gmail.com
Emergency Contact: Franklyn Warren
(818) 317-6757

Vihra Gocheva

Cell Phone: 925-262-7326
email: vgocheva@gmail.com
Emergency Contact: Nedko Nedev
(925) 705-6863

Katherine Wilson

Cell Phone: 330-921-5777
email: k8tw1lson.1115@gmail.com
Emergency Contact: Debbie Wilson
(330) 921.8122

Ralph Rasalan

Cell Phone: 805-268-6855
email: rrasalan@gmail.com
Emergency Contact: Cesar Marquez
(510) 520-8450

Matthew Beristianos

Cell Phone: 415-264-0243
email: mberistianos@alliant.edu
Emergency Contact: Megan Fu
(415) 810-3455

Tori Strong

Cell Phone: 530-321-5088
email: tjlove2u@yahoo.com
Emergency Contact: Cindy Peek
530-520-3319 / 530-872-3210

Linda Mora

Cell Phone: 650-452-4278
email: lbmora@gmail.com
Emergency Contact: Armando Mora
650-922-2298